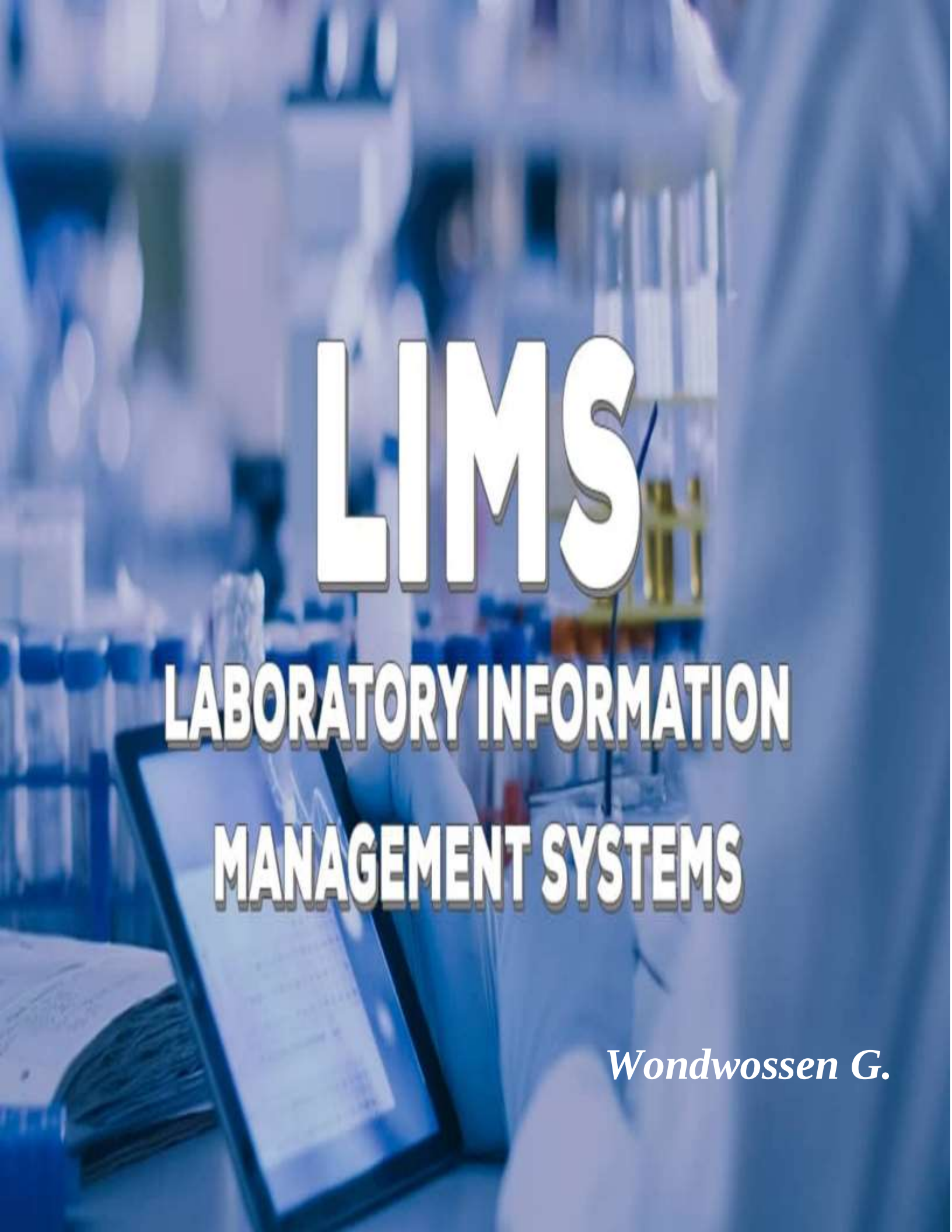
LIMS
LABORATORY INFORMATION
MANAGEMENT SYSTEMS
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Laboratory Information Management System in National Quality Control Laboratory

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Table Content

1 Introduction

- With the increasing complexity of health product regulation and the growing volume of samples for testing, there is a pressing need for robust laboratory information management. The proposed LIMS will automate and optimize laboratory workflows, ensuring efficient sample management, data integrity, and regulatory compliance. Scientific and commercial laboratories can enhance various QC and quality assurance procedures by using LIMS software to automate the entry of data from instruments and record, manage, and organize large collections of data for quick search and retrieval. The benefits of deploying LIMS are undeniable. Proper planning and communication from the start may protect against common LIMS implementation challenges such as longer schedules, scope creep, unanticipated expenses, and poor user engagement.
- Productivity and efficiency are both increased by the LIMS supported automation of the entire procedure. Less manual work is required at every stage of the procedure, which also lowers the possibility of human error. As a result, laboratories become more focused on results and have better access to their clients' knowledge and talent.
- As a matter of fact, LIMS significantly improves and streamlines lab work by providing lab technicians with straightforward yet useful functions that allow them to operate more productively and efficiently and motivate them to offer their best rather than waste their time on needless and difficult operations.
- LIMS frees lab employees from time-consuming chores by handling many of them automatically. For instance, when used to speed up the laboratory process, LIMS can automatically assign tasks to researchers or show the location of a sample's next destination. LIMS also has the capacity to streamline and automate laboratory inventory management.
- Additional LIMS capabilities include inventory management and equipment management. LIMS also provides a solution for the problem of instrument calibration and maintenance. It provides the opportunity to schedule necessary maintenance chores and lab instrument calibrations and keeps track of all related procedures.
- The integration of WHO, ISO 17025, and ISO 90012015 into a Laboratory Information Management System (LIMS) offers significant advantages in terms of efficiency, data integrity, compliance, and overall quality management. The integration of ISO 17025

requirements into a Laboratory Information Management System (LIMS) offers significant advantages, including enhanced efficiency, data integrity, compliance, and marketability.

- By leveraging LIMS,
    - Laboratories can streamline their operations, ensure ongoing compliance with ISO 17025, and maintain high standards of quality and reliability in their testing and calibration activities.
    - Laboratories can ensure adherence to international standards, enhance their operational efficiency, and build trust with customers and regulatory bodies.
- This comprehensive approach not only supports the achievement of accreditation but also fosters a culture of excellence and continuous improvement in laboratory operations.
- The LIMS lifecycle described in this guide includes the following phases:
    - Project initiation,
    - Requirements analysis,
    - Design,
    - Build/configure,
    - Test and commission,
    - Operation and maintenance, and
    - Retirement.

Benefits of introducing LIMS to NQCL

- The introduction of a LIMS in to NQCL offers numerous benefits that enhance operational efficiency, data integrity, compliance, and overall laboratory performance. By leveraging automation, robust data management, and standardized processes, the NQCL can improve the quality and reliability of drug testing, ensuring public health and safety. This transformative system not only supports the authority in meeting international standards but also fosters a culture of continuous improvement and transparency, ultimately strengthening the regulatory framework and public trust.

Enhanced Operational Efficiency

- Automation of routine tasks:
    - Automation of sample tracking, data entry, and result processing reduces manual workload and minimizes human errors.

    - Streamlined workflows lead to faster processing times and increased laboratory throughput.
- Resource optimization:
    - Efficient scheduling and utilization of laboratory resources, including equipment and personnel.
    - Automated inventory management ensures optimal use of reagents and supplies, reducing waste.

Improved data integrity and accuracy

- Accurate data entry:
    - Integration with laboratory instruments for automatic data capture ensures high accuracy and reduces the risk of transcription errors.
    - Standardized data entry forms with validation checks maintain data consistency.
- Comprehensive audit trails:
    - Detailed audit trails provide complete records of all data modifications and user activities.
    - Ensures traceability and accountability for all laboratory processes.

Enhanced compliance and regulatory adherence

- ISO 17025 compliance:
    - Aligns laboratory practices with ISO 17025 standards, ensuring the quality and reliability of test results.
    - Facilitates regular audits and inspections with well documented processes and records.
- WHO guidelines adherence:
    - Supports adherence to WHO guidelines for quality control and reporting, ensuring international standards are met.
    - Ensures that laboratory operations and outputs meet global regulatory requirements.

Increased data security and confidentiality

- Robust security measures:

- Implementation of multifactor authentication (MFA) and role-based access control (RBAC) secures sensitive data.
- Encryption of data at rest and in transit protects against unauthorized access and breaches.

- Secure data storage:
  - Centralized data storage with regular backups ensures data is protected and recoverable in case of system failures.
  - Tamperproof audit logs safeguard the integrity of records.

Enhanced reporting and decision-making

- Real-time data access:
  - Provides real-time access to laboratory data and test results, enabling timely decision-making.
  - Dashboards and analytics tools offer insights into laboratory performance and trends.
- Automated reporting:
  - Generates standardized and customizable reports for internal and external stakeholders.
  - Facilitates efficient regulatory reporting and compliance documentation.

Improved quality control and assurance

- Standardized protocols:
  - Implementation of standardized protocols and procedures ensures consistency in testing and results.
  - Facilitates continuous monitoring and improvement of quality control processes.
- Corrective and preventive actions:
  - Systematic tracking and management of nonconformities and deviations.
  - Enables timely corrective and preventive actions to maintain high standards of quality.

Enhanced traceability and transparency

- Comprehensive sample tracking:

    - End to end tracking of samples from receipt to disposal, maintaining a clear chain of custody.
    - Transparent processes improve trust and accountability.
- Detailed documentation:
    - Centralized and accessible documentation of all laboratory activities and procedures.
    - Ensures transparency and easy access to information for audits and inspections.

Facilitated collaboration and communication

- Centralized information sharing:
    - Centralized platform for sharing data and reports within the laboratory and with external partners.
    - Enhances collaboration and communication across different departments and stakeholders.
- Integrated workflows:
    - Integrated workflows promote seamless coordination between laboratory functions and external entities.
    - Supports effective communication and information exchange.

Support for continuous improvement

- Performance monitoring:
    - Real-time monitoring of laboratory performance metrics and key indicators.
    - Identifies areas for improvement and optimization.
- Feedback mechanisms:
    - Systematic collection and analysis of feedback to drive continuous improvement.
    - Encourages a culture of learning and quality enhancement.

Public health and safety assurance

- Reliable drug testing:
    - Ensures the accuracy and reliability of drug testing, safeguarding public health.
    - Reduces the risk of substandard or counterfeit drugs entering the market.
- Timely decision-making:

- Enables timely regulatory actions based on accurate and comprehensive data.
- Enhances the authority's ability to respond to public health emergencies and drug safety issues.

1.1 Objective

1.1.1 General objectives of LIMS

- The introduction of a LIMS in the National Quality Control Laboratory (NQCL) aims to significantly enhance the quality and safety of drugs for public use. By ensuring accurate and reliable testing, improving efficiency and productivity, and facilitating compliance with international standards, a LIMS will play a crucial role in promoting public health and safety.
- LIMS system will support the laboratory in delivering high quality services, ensuring that only safe and effective drugs reach the market, ultimately protecting the health and wellbeing of citizens. This document provides a high-level "holistic" guide that the NQCL in developing a request for proposals (RFP) for a LIMS purchase or implementation.
- The following, but not limited to, are the primary business needs that justify LIMS implementation in NQCL

Ensuring accurate and reliable drug testing

- Implement a Laboratory Information Management System (LIMS) to enhance the accuracy and reliability of drug testing processes.
- Integrate complex analytical instrumentation and automation into data entry, collection and reporting thereby reducing human error
- Maintain accurate and consistent records of test results.
- Provide validation and verification mechanisms to ensure the integrity of testing data.

Enhancing data integrity and traceability

- Ensure data integrity and traceability of all laboratory processes and results.
- Use audit trails to track all data modifications and access.
- Implement role-based access control to secure sensitive information.
- Ensure traceability of samples from receipt to disposal, maintaining a clear chain of custody.

Compliance with International Standards and Guidelines

- Ensure the laboratory meets international standards such as ISO 17025 and adheres to WHO guidelines.
- Align laboratory processes with ISO 17025 requirements for testing and calibration.
- Generate reports and documentation that comply with WHO guidelines.
- Facilitate regular audits and inspections through comprehensive documentation and traceable records.

Improving efficiency and productivity

- Increase the efficiency and productivity of laboratory operations through automation and streamlined workflows.
- Automate routine tasks such as sample tracking, result entry, and reporting.
- Optimize resource allocation and minimize turnaround times for testing.
- Enable real-time monitoring of laboratory activities and performance metrics.

Enhancing quality control and assurance

- Strengthen quality control and assurance processes to ensure the consistency and reliability of drug testing.
- Implement stringent quality control protocols and automated checks.
- Provide a centralized system for managing standard operating procedures (SOPs) and guidelines.
- Facilitate corrective and preventive actions through detailed tracking and reporting of nonconformities.

Facilitating data driven decision making

- Enable data driven decision-making by providing accurate, comprehensive, and real-time data.
- Generate detailed analytical reports and visualizations to identify trends and insights.
- Provide decision makers with access to up-to-date information on laboratory operations and test results.
- Support regulatory decision-making processes with reliable data.

Enhancing collaboration and communication

- Improve collaboration and communication within the laboratory and with external stakeholders.
- Provide a centralized platform for sharing data and reports with internal and external stakeholders.
- Facilitate collaboration between different departments and laboratories through integrated workflows.
- Enable secure and efficient communication channels for regulatory reporting and compliance.

Strengthening public health and safety

- Ensure the safety and efficacy of drugs available to the public by enhancing the quality control processes.
- Conduct rigorous testing and validation of drug quality, safety, and efficacy.
- Provide timely and accurate information on drug quality to regulatory authorities.
- Ensure that only drugs that meet the highest standards of quality and safety are approved for public use.

Supporting regulatory compliance and reporting

- Ensure compliance with national and international regulatory requirements and facilitate efficient reporting.
- Automate the generation of regulatory reports and submissions.
- Maintain comprehensive records and documentation to support regulatory audits and inspections.
- Provide a robust system for tracking and managing regulatory compliance activities.

Facilitating continuous improvement

- Promote continuous improvement in laboratory processes and quality management systems. Implement feedback mechanisms to identify areas for improvement.
- Use data analytics to monitor performance and identify opportunities for optimization.
- Encourage a culture of continuous learning and improvement within the laboratory.

1.1.2 Specific objective of LIMS to MQCL

- To minimize transcription errors by limiting manual data entry
- To use of barcodes to track samples
- To reduce turn-around-time by streamlining the assigning of worksheets to QC analysts, minimizing data entry
- To enhance rapid dissemination of results to NQCL customers through electronic media (email/fax/text message).
- To improve traceability by logging all actions performed at each location
- To securely store data, to view trends and to generate quality control charts
- To generate statistical reports for planning and monitoring purposes.

2 Laboratory Work Flow

- LIMS remains a critical part of the infrastructure of any pharmaceutical manufacturing organization. Today's LIMS goes far beyond just the management of samples, tests, and results. It also provides resource management, allowing organizations to forecast fewer sample volume and resource needs.
- It provides dashboard views that allow organizations to see how their lab is operating and identify any data that are trending toward warning or failure limits.
- Lab work flow shows both the logical dataflow through the LIMS process in combination with the corresponding physical sample processes.
- ***The Sample Lifecycle*** is an integral part of laboratory operations and encompasses three distinct phases:
    - Pre-Analytical,
    - Analytical and
    - Post-Analytical.
- Managing the sample lifecycle effectively is essential to ensure accurate results and avoid any leaks or errors due to poor sample management.

2.1 Pre-Analytical phase

- The Pre-Analytical phase begins when a test order is placed and the sample is collected. The sample goes through the process of accession, where it is acknowledged or rejected for testing. If the sample is accepted, it is then segregated based on the type of sample and the department

Sample Analysis Request

- The workflow process is initiated by a request for sample analysis. Examples of sample requests include manual forms, phone requests, time or calendar-based requests, process driven requests, and LIMS generated requests. Information obtained from a sample request includes client information, sample information, required tests, and safety information.

Sample Collection

- Sample collection may be a manual or automated process.
- The condition of the sample that comes into the laboratory should be able to be documented.
- Examples include notations of preservation, temperature of sample, and the condition of sample containers.
- Sample collection can be assisted by printing collection lists and generating labels for sample containers.

Sample Login

- The LIMS assigns a unique laboratory ID number to each sample logged into the LIMS.
- The system can capture who submitted the sample, costs, test required, and priority of the sample.

Distribute Samples

- The sample distribution process includes LIMS functions of work lists, sample routing, custody, and labeling.
- It is sometimes necessary to divide the sample for simultaneous analysis at different workstations.

Schedule Work

- LIMS automatically schedules work (tests) for each sample. Lab management can adjust sample priorities and reassign work as required.
- LIMS can add laboratory standards, control samples, and quality control samples to the scheduled workflow. LIMS statuses are updated for each sample.

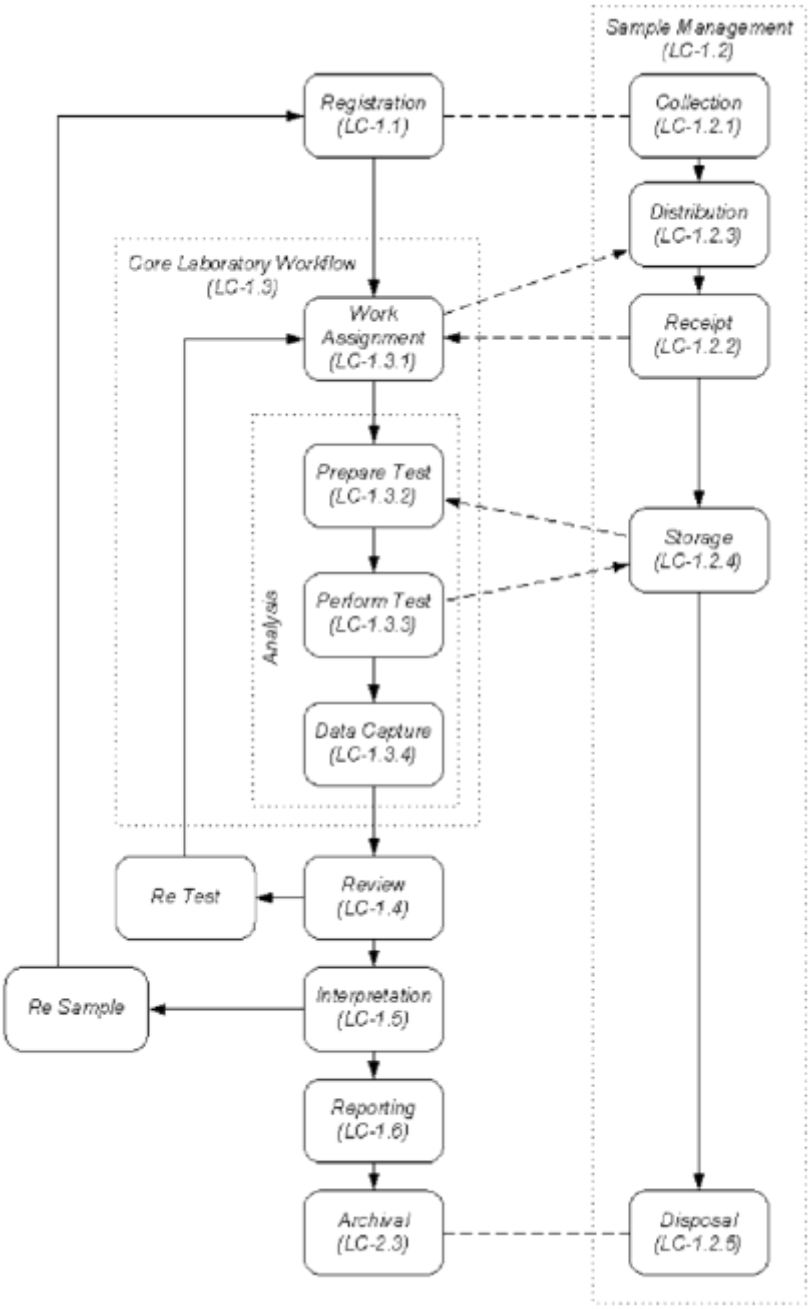

Figure 21 Generic LIMS workflow in Sample lifecycle. *Source: ASTM*

2.2 Analytical phase

- The Analytical phase is a step of utmost importance, in the sample lifecycle, where the collected and segregated sample undergoes the ordered test and results are generated. In this phase, the laboratory staff will be responsible for selecting the appropriate test methods, preparing the samples, running the tests and ensuring that the recorded results are accurate, precise and consistent.

Analysis

- Analysis involves multiple steps: sample preparation, sample measurement, quality control samples, and data capture.

Sample Preparation

- Most samples need some preparation before undergoing analysis. In some cases, preparation requires entering experimental data such as tear weight and final weight from a balance.

Sample Measurement

- Test results are the main output of the measurement process.
- Results may also be obtained for blanks, standards, and instrument self-checks.
- The results of sample analysis must be entered into the LIMS.
- Data may be entered manually or through an electronic interface where data are transferred from the instrument directly into the LIMS.
- When results are entered into the LIMS, the status of the sample is updated.
- Audit trails record information about each LIMS transaction.

2.3 Post-Analytical phase

- The Post-Analytical phase is the final and crucial step in the sample lifecycle, where the test results are reviewed and verified for accuracy and completeness by a professional. The final report is then generated and delivered for approval.

Verification and Correction

- A laboratory may require that a qualified person review result.

- The LIMS can show summaries of work done for review.
- Unusual or out of range results can be flagged for greater scrutiny.
- Corrections to data can be made in the verification step.
- Changes to results should be audit trailed. Results can be approved, thus changing the sample status.
- Results can also be marked as not acceptable and enter a retest loop or a resample loop.

Reports

- Once test results are verified and approved, they can be reported to the customer. Reports can take a variety of forms: printed output, electronic mail, and response to online queries.
- Different reports can be generated to meet different requirements.
- Existing reports may include certificates of analysis, work schedules, customer test reports, daily sample analysis reports, quality control reports, and backlog reports, and lab production reports.
- Evaluation of current reports will give additional insight into the type of information that will need to be entered into LIMS, stored in, and retrieved from the LIMS.
- The examination of a sample analysis report may indicate that customer information needs to be stored in the LIMS.
- Test types and sample types will therefore need to be stored.
- Test results, both numerical and descriptive, must be able to be entered into the LIMS.
- All information must be able to be retrieved quickly.

Interpretation

- The laboratory exists to generate information for their clients.
- The LIMS can organize and configure results to make reporting and interpretation easier. Statistical routines can be used to determine trends and data can be shared across departments and business units for enhancing decision making.

Disposal of Samples

- The proper documentation of sample disposal following analysis is an increasing concern. The LIMS can be used to track final sample disposition and waste removal. The LIMS can

be used to track final sample storage, disposal, and waste removal, or it can alert end-users if any samples are to be returned following analysis.

3 LIMS and Guidelines and Standards

3.1 LIMS and ISO and WHO

- ISO/IEC 17025 is the international standard that specifies the general requirements for the competence of testing and calibration laboratories. It covers testing and calibration performed using standard methods, nonstandard methods, and laboratory developed methods. ISO 17025 emphasizes a laboratory's ability to produce precise and accurate test and calibration data, which is crucial for ensuring reliable results and maintaining high standards in laboratory operations.
- ISO 17025 documentation involves a structured approach to quality management systems (QMS) in laboratories, focusing on both technical competence and management requirements. The World Health Organization (WHO) provides guidelines for National Quality Control Laboratories (NQCLs) to ensure the quality, safety, and efficacy of medicines. These guidelines focus on establishing robust systems for testing and quality assurance in national laboratories.
- ISO/IEC 17025 is the international standard that outlines the general requirements for the competence of testing and calibration laboratories. Accreditation to ISO 17025 demonstrates that a laboratory operates competently and generates valid results, thereby promoting confidence in its work both nationally and internationally.
- ISO15189 Medical laboratories; requirements for quality and competence is an international standard that specifies the quality management system requirement particular to medical laboratories. The standard was developed by the international organization for Standardization's Technical Committee (ISO/TC 212)
- The key elements of ISO 17025 and WHO NQCL include
    - *Quality Management Systems (QMS)* Implementation of a comprehensive QMS to manage and document laboratory processes, ensuring consistent and reliable results.

- *Quality manual*; a document that defines the laboratory's quality policy and the scope of the QMS. The system should support documented procedures for laboratory operations in line with ISO 17025.
- *Data Integrity:* ensuring the accuracy and reliability of data through validation checks and controlled access.
- *Standard Operating Procedures (SOPs)*; detailed procedures for all laboratory processes, ensuring consistency and reliability.
- *Work instructions*; specific instructions for performing individual tasks within the laboratory.
- *Records and Forms*; documentation of all laboratory activities, including test results, calibration data, equipment maintenance, and personnel training records.
- *Audits*; Comprehensive audit trails to track all modifications and accesses to data. Detailed logs of all user activities, including login/logout, data access, modifications, and deletions.
- *Good Laboratory Practices (GLP)* Adherence to GLP to maintain the quality and integrity of laboratory data.
- *Proficiency Testing and Calibration* Regular proficiency testing and calibration to ensure accuracy and reliability of test results.
- *Personnel Training and Competence* Continuous training and evaluation of laboratory personnel to maintain high levels of competence.
- *Equipment and Facilities Management* Proper maintenance and calibration of laboratory equipment and facilities.
- *Sample Management* Efficient handling, storage, and tracking of samples to maintain their integrity and traceability.
- *Management Requirements* Focus on the effectiveness of the management system within the laboratory. Regular evaluations to ensure the QMS is functioning effectively and identifying areas for improvement.
- *Technical Requirements* Address the competence of staff, methodology, test/calibration methods, equipment, and the quality of test and calibration results.

ISO 17025 certification

- The aim of the ISO 17025 standard is to provide laboratories with guidelines for continuously improving their quality through a quality management system. The focus of the ISO standard is the reliability and quality of test methods. The aim is also to strengthen acceptance and confidence in the work of laboratories.
- Especially for contract laboratories offering independent calibrations or sample testing, ISO 17025 certification is proof of the ability to produce consistently reliable and trustworthy results.

ISO/IEC 17025 accreditation requirement

- In order to comply with accreditation, it is mandatory that the certified laboratory is regularly accredited by an external and official audit. The accreditation body assesses all the requirements of ISO/IEC 17025 and verifies that the laboratory complies with the standard.
- ISO 90012015 is an international standard that specifies requirements for a quality management system (QMS). Organizations use the standard to demonstrate their ability to consistently provide products and services that meet customer and regulatory requirements and to enhance customer satisfaction through the effective application of the system, including processes for improvement and the assurance of conformity to customer and applicable statutory and regulatory requirements.
- In order to be accredited, a number of requirements must be met. In addition to general and structural requirements for the laboratory, there are also requirements for resources, processes, and management. The management requirements are largely in line with the ISO 9001 standard, while ISO 17025 refers specifically to laboratories, their test methods, and calibrations.

3.2 LIMS and FDA 21CFR part 11

- FDA 21CFR part 11 is the part of title 21 of the Code of Federal Regulations that establishes the United States Food and Drug Administration (FDA) regulations on electronic records and electronic signatures (ERES).

- FDA 21 CFR Part 11 as it is commonly called, defines the criteria under which electronic records and electronic signatures are considered trustworthy, reliable and equivalent to paper records
- GLP is a set of principles that are intended to assure the quality and integrity of nonclinical laboratory studies that are intended to support research or marketing permits for products regulated by government agencies.
- GLP specifically refers to a quality system of management control for research laboratories and organization to ensure the uniformity, consistency, reliability, reproducibility, quality, and integrity of chemicals, nonclinical safety tests from physiochemical
- properties through accurate to chronic toxicity tests

3.3 LIMS and ISPE GAMP 5

- ISPE GAMP 5 (Good Automated Manufacturing Practice) provides guidelines for the validation of automated systems, including LIMS. ISPE GAMP 5 is a guideline that focuses on the lifecycle management of automated systems in regulated environments. It emphasizes a risk-based approach to validation and integrates concepts from the entire system lifecycle, from conception to decommissioning. LIMS in line with GAMP 5 Category 4 requires extensive configuration and customization, demanding a comprehensive validation approach. This includes thorough documentation, rigorous testing, structured change control, and ongoing maintenance. GAMP 5 Category 4 systems are:
    - **Highly Configurable and Customizable:** These systems often require significant user input to configure or customize to meet specific operational needs.
    - **Significant Validation Effort:** Due to the extensive customization, Category 4 systems demand rigorous validation to ensure that they meet all specified requirements and comply with regulatory standards.

LIMS and GAMP 5 Principles

- The implementation of LIMS should be guided by a risk-based approach, assessing the impact of the system on product quality, patient safety, and data integrity. In addition, high-risk processes and functionalities should receive more rigorous validation efforts, while lower-risk elements may be subject to a more streamlined validation approach. Carefully

control any customizations to the LIMS to prevent introducing risks. Customizations should be documented, validated, and controlled through formal change management processes.

- LIMS configurations should be managed carefully to ensure that they meet the system's intended use and regulatory requirements. This involves documenting changes, validating configurations, and managing software updates. Implement robust management practices to handle configuration settings, ensuring they align with regulatory requirements and are documented thoroughly. Moreover, customizations should be limited and controlled, as they can introduce complexity and potential risks. Any customizations should undergo a formal validation process.
- Documentation Maintain thorough documentation throughout the LIMS lifecycle, including configuration records, test results, change control documentation, system specifications, validation protocols, and user manuals. Besides, LIMS complies with relevant regulatory standards and guidelines, such as those from the FDA, EMA, and other regulatory bodies.
- Ensure appropriate security measures to protect sensitive data and prevent unauthorized access. Implement security measures to protect sensitive data and ensure compliance with regulatory requirements. to ensure the accuracy, consistency, and reliability of data managed by the LIMS. This includes access controls, audit trails, and data protection mechanisms.
- LIMS vendors that provide systems and support should aligned with GAMP 5 principles. Work closely with the LIMS vendor for support and maintenance, particularly if customizations or configurations affect the standard functionalities.
- QC analysists should be engaged as early as possible in the validation process to ensure that the LIMS meets their needs and expectations and also, they understand how to operate the configured and customized LIMS effectively. The NQCL should implement a robust change management process to handle updates and modifications to the LIMS.

System Lifecycle

- Define the objectives and scope of the LIMS, including how it will manage and track samples, data, and workflows.
- Ensure that the design and development of the LIMS are aligned with the URS. outlining the specific needs and requirements for the LIMS. This should reflect the extensive customization and configuration needs. This includes validating the design to ensure it meets

user needs including functional requirements, performance criteria, and data management needs.

- Ensure the design of the LIMS meets the specified requirements, with appropriate controls for software development and configuration.
- Conduct comprehensive testing, including Installation Qualification (IQ), Operational Qualification (OQ), and Performance Qualification (PQ). Testing should address both standard functionalities and any customizations or configurations.to ensure the LIMS performs as expected.
- Implement procedures for ongoing maintenance, updates, and changes, adhering to GAMP 5 principles. Implement a structured change management process to handle updates, modifications, and customizations to the LIMS. This includes assessing the impact of changes, updating documentation, and re-validating as necessary.
- Additionally, for any proposed changes, perform a risk assessment to determine the potential impact on system functionality, data integrity, and compliance. Moreover, follow a formal process for decommissioning the LIMS, ensuring data integrity and regulatory compliance.

4 Application of LIMS

- LIMS plays a crucial role in achieving and maintaining ISO and WHO standards. Moreover, it can significantly enhance the implementation of ISO and WHO standards by providing a comprehensive platform for managing all laboratory processes and ensuring compliance with international standards. Besides, it ensures the quality and safety of pharmaceuticals by managing analytical data for drug development, manufacturing, and quality control. As a result, the integration of LIMS into QC laboratories has become essential for ensuring data integrity, improving efficiency, and maintaining regulatory compliance. By automating tasks, streamlining workflows, and providing valuable data insights, LIMS empowers analytical chemists to focus on their core expertise and deliver accurate, reliable results.

Quality Assurance and Control

- The majority of lab procedures are under the control of LIMS, guaranteeing the highest level of quality. Furthermore, based on the type of lab, LIMS performs effective quality checks on samples or products. Additionally, LIMS automates the logging of samples or

products and rapidly extracts management information to guarantee complete process control. All relevant QC data, such as spikes, duplicates, and blanks, are entered and processed in the same way that live samples are, but with the addition of QC calculations and automatic QC limit testing against predetermined limits. This QC data is "linked" to all appropriate samples automatically. This important relationship enables the laboratory to integrate entire QC data in automated reports, electronic deliverables, and online date services.

- LIMS can automate and streamline the implementation of SOPs, ensuring that all laboratory processes adhere to the defined standards. The LIMS system can manage and track all quality control (QC) samples, standards, and reference materials, providing a comprehensive QC environment.

Leadership and Commitment

- LIMS can help disseminate the quality policy to all employees, ensuring awareness and alignment with organizational goals. LIMS can define and document roles, responsibilities, and authorities within the system.

Resource Management

- LIMS can track and manage resources, ensuring that personnel, equipment, and materials are used efficiently and effectively. Additionally, it tracks and manages training records, ensuring all personnel are competent and their skills are uptodate.

Operational Control* and *Performance Evaluation

- All analytical data collected from automated instruments are sent to LIMS electronically rather than manually, avoiding the inevitable transcription errors that can occur when manually entering large amounts of data. It also streamlines and automates laboratory processes, ensuring consistency and compliance with established procedures. LIMS manages and monitors external suppliers, ensuring the quality of externally provided processes, products, and services.
- LIMS provides tools for monitoring and measuring key performance indicators, ensuring alignment with quality objectives. It schedules and documents internal audits, ensuring regular review and compliance with ISO 90012015 requirements. LIMS assists in planning

and documenting management reviews, facilitating informed decision-making and continuous improvement.

Continuous Improvement

- LIMS tracks and manages nonconformities and corrective actions, ensuring timely resolution and prevention of recurrence. In addition, it provides mechanisms for collecting and analyzing feedback, supporting ongoing improvement efforts.

Data Management and Integrity

- Using the quick and dependable interfaces of LIMS, a lab technician can implement data with ease. This functionality facilitates data entry and enables it to be customized to the tastes and needs of a specific lab.
- LIMS features the ability for lab technicians to schedule and generate reports among many other features. To satisfy the requirements or rules of labs, they can be prepared in a particular, necessary format. Additionally, the report can be sent to specific people or groups after it has been created, enabling seamless and quick information delivery.
- LIMS ensures accurate and secure data capture, storage, and retrieval, which is essential for ISO 17025 compliance.
- It facilitates the electronic storage of all documentation, including test results, calibration records, and audit trails, ensuring data integrity and traceability.

Audit and Compliance

- LIMS and other laboratory software must comply with regulatory requirements, including 21 CFR Part 211.68 and ICH Q7 Guidance for Industry. The software validation process should confirm compatibility with **COTS software** for laboratory instruments and ensure proper data transmission and security measures.
- LIMS can automate the scheduling and documentation of internal audits and management reviews, ensuring continuous compliance with ISO 17025 requirements. An audit trail is a basic LIMS feature required for regulated laboratories, although it can be beneficial to any laboratory.

- Audit trails allow lab personnel to follow the audit path from start to finish, explicitly identifying the collaborator and the precise time of specific actions, or automating the audit process.
- LIMS can automate and control the audit process, ensuring that all regulations are met, and all stages are taken. It also detects abnormalities and reports them instantly to limit potential damage.
- The system can generate audit trails and reports that are necessary for external audits and accreditation processes.
- LIMS schedules and documents internal audits, ensuring that all aspects of the laboratory's operations are regularly reviewed and compliant with ISO 17025 requirements.
- LIMS assists in planning and documenting management reviews, which are necessary for continuous improvement and compliance.

Document Control

- LIMS provides robust document control functionalities, allowing laboratories to manage version control, approval workflows, and distribution of SOPs and other critical documents.
- LIMS ensures that only the latest, approved versions of documents are used in laboratory operations, reducing the risk of errors and noncompliance.

Quality Management

- LIMS manages and controls all documentation required by ISO 17025, ensuring that only the latest versions are available to users.
- LIMS provides a platform to create, store, and manage Standard Operating Procedures (SOPs) and protocols, ensuring consistency and adherence to the established methods.

Good Laboratory Practices (GLP)

- LIMS ensures that SOPs are easily accessible and adhered to by all personnel, promoting consistency and compliance with GLP.
- LIMS maintains the integrity of laboratory data by providing secure, tamperproof storage and robust data management protocols.

Data Management

- In the typical laboratory, various types of data are gathered and kept. There are specifications, safety guidelines, regulatory information, and reports available. The addition of the capacity to create, maintain, import, and export other sorts of data was a logical but also very helpful decision given that LIMS is already capable of managing sample and experiment data.
- LIMS ensures data integrity through secure, electronic records that are protected against unauthorized access and modifications. Moreover, LIMS maintains a complete audit trail of all actions taken on the data, ensuring full traceability from sample receipt to final report.

Proficiency testing

- LIMS gives lab technicians the chance to schedule and plan training in addition to managing work schedules and storing employee data. Additionally, it can track and manage personnel training records, ensuring that all staff members are competent and trained according to ISO 17025 requirements. The system can alert management when training or recertification is due, ensuring continuous staff competency.

Personnel and Workload Management

- The ability to schedule duties and events is provided by LIMS, which streamlines the workload management procedure. Technicians can be given workloads, and maintenance plans can be made. LIMS can easily optimize all duties and streamline all lab operations

Method Management

- The LIMS is the single location where all laboratory operations, procedures, and methodology are managed. It organizes and simplifies every lab procedure. In addition, LIMS instructs lab technicians on how to complete their current duties.

Equipment and Calibration Management

- It might be difficult to keep track of all the procedures involved in instrument calibration and maintenance, especially in a setting laboratory. LIMS manages calibration schedules and records, ensuring that all instruments are calibrated and fit for purpose.

- Additionally, LIMS keeps thorough records of such actions and enables lab staff to continuously check the technical performance of lab equipment.
- LIMS provides the ability to schedule crucial lab instrument calibrations and maintenance procedures ensuring that equipment is properly maintained and calibrated.

Sample Management

- LIMS is used to assign a job and create the bottle labels for all samples as soon as they arrive at the laboratory. All necessary sample information, including the tests to be run, must be entered during the sample login to complete the information. Even very long client sample identifiers can be captured by the sample login process.
- All sample scheduling and prioritization are managed by LIMS. This guarantees that all samples, even urgent and emergency samples, receive the proper attention from all lab departments. This covers crucial concerns like turnaround and hold times.
- LIMS provides complete traceability of samples, from receipt through testing to final reporting. The importance of the chain of custody varies depending on the laboratory.
- *Chain of Custody* is a crucial aspect of the operations of highly regulated laboratories. COC is an accurate written record that tracks the possession, transfer, handling, and location of samples with sample lifecycle. The COC is an important function of sample control and an integral part of sample receipt. LIMS display any inventory transactions for the sample (view history of how a sample has been handled). LIMS ensures a documented chain of custody for all samples, which is crucial for maintaining the integrity of test results. It is critical to retain and access information such as user ID or location ID to maintain successful CoC.

Customer Relationship Management

- Client demographic information is stored and managed by LIMS. It also streamlines and simplifies communication with linked clients. Furthermore, certain LIMS allows the client to request a sample from the LIMS.
- The sample container can then be registered and sent to the client as the next step. The sample can then be collected and delivered to the lab.

4.1 Advantages of LIMS

Time Tracking

- The general ability of LIMS to monitor how much time an employee spends at work is referred to as the time tracking function. Payroll related uses for it are possible.
- Additionally, this feature can be used for projects and tasks that are more particular, and it aids in employee work evaluation programs by showing how quickly employee's complete tasks and how much time they spend on each task.

Barcode Handling

- Handwritten labels can be completely replaced by barcodes. Bar code technology also allows laboratories to increase the amount of information available on the sample label, storing both text and numeric values. This information can easily be uploaded to the LIMS, thus avoiding double entry. Because bar codes can greatly increase the overall efficiency of sample and data management Bar coding is about 20 times faster and 20,000 times more accurate than keyboard entry.
- Barcodes enable lab staff with more precise data input, tighter sample instrument and sample study linkages, and greater label space. Aside from the ability to design and print labels, a LIMS may also support a range of barcode readers.

Enhanced Credibility and Marketability

- ISO 17025 accreditation is recognized internationally, enhancing the credibility and marketability of the laboratory. Accreditation assures customers of the laboratory's commitment to quality and competence.

Improved Compliance and Standardization

- Laboratory data management software, including LIMS, must be validated for compliance with regulations such as 21 CFR Part 11. Users are responsible for ensuring that software functionality, features, and capabilities meet regulatory standards.
- LIMS can be used in laboratories across a wide range of sectors to organize and analyze data on samples, tests, and test results, among other things. Compliance is critical since failure to comply with the regulations is likely to result in massive losses and falsifications. Regular internal audits and management reviews, supported by LIMS, ensure the QMS

remains effective and compliant. LIMS ensures compliance with WHO by integrating ISO 17025 guidelines and other international standards, facilitating regulatory approvals and accreditation. LIMS enforces standardized procedures across the laboratory, promoting consistency and reliability in test results.

Enhanced Efficiency and Productivity

- LIMS automates routine tasks and processes, reducing manual workload allowing laboratory personnel to focus on critical analysis and research activities by increasing productivity. *Consistent automated data handling* ensures consistency and accuracy in results. LIMS streamlines laboratory workflows; automated data entry minimizes errors and enhance productivity minimizing delays and bottlenecks.

Regulatory Compliance

- LIMS enables meeting legal requirements such as ISO 17025 accreditation helps laboratories meet legal and regulatory requirements, reducing the risk of noncompliance. Besides, it facilitating audits and makes it easier to prepare for and pass external audits by maintaining organized and accessible records.

Effective Quality Control

- The QC Management module allows to log and track quality control samples. LIMS manages all aspects of quality control, including QC samples, standards, and results, ensuring the accuracy and reliability of test data. LIMS provides tools for continuous monitoring and analysis of QC data, supporting ongoing quality improvement.

Operational Transparency and Accountability

- LIMS maintains comprehensive audit trails for all laboratory activities, enhancing transparency and accountability. Realtime reporting and access to data and reports enables better decision-making and oversight.
- LIMS provides comprehensive recordkeeping and document control provide full traceability of all laboratory activities, from sample receipt to final reporting. It enhances transparency by providing easy access to documentation and data, supporting effective decision-making.

Risk Management and Continuous Improvement

- Regular audits and reviews facilitated by LIMS help identify and mitigate risks.
- LIMS supports a culture of continuous improvement by providing tools to monitor performance and implement corrective actions.
- LIMS supports proactive risk management by providing tools for monitoring and mitigating risks.

Cost Savings

- LIMS increased efficiency through automation and streamlined processes leads to cost savings. LIMS reduced errors and lower the costs associated with rework and noncompliance.

Enhanced Data Integrity and Security

- LIMS provides secure, electronic storage of all laboratory data, protecting it from unauthorized access and tampering. Electronic records and secure data storage ensure the integrity and confidentiality of laboratory data.
- LIMS maintains comprehensive audit trails, ensuring the integrity and traceability of data. Automated audit trails and data validation processes enhance data accuracy and compliance.
- The following general principles are foundational to establishing robust data integrity in LIMS:
    - Controls should be established to cover the entire data lifecycle from data collection to use in GXP reports and archiving.
    - The data lifecycle extends through retention, archival/retrieval, and destruction.
    - The data lifecycle should be reevaluated for risk and the appropriateness of risk mitigation controls every time the laboratory evolves from a manual to a hybrid and/or electronic instrument or experiences a change in the data capture process or the workflow in the laboratory

Customer Confidence and Market Competitiveness

- ISO 17025 accreditation, supported by robust LIMS documentation, enhances customer confidence in the laboratory's ability to deliver reliable and accurate results. Compliance

with international standards can open up new market opportunities and enhance the laboratory's competitive edge.

Risk Management and Continuous Improvement

- Regular audits and reviews facilitated by LIMS help identify potential risks and areas for improvement, supporting proactive risk management. Continuous monitoring and improvement of laboratory processes enhance overall quality and performance.

5 LIMS technical evaluation

- Evaluating a LIMS for a pharmaceutical national quality control laboratory involves considering a wide range of technical specifications to ensure the system meets regulatory requirements, enhances laboratory efficiency, and maintains data integrity.
- Evaluating a LIMS against these criteria ensures that the chosen system will meet the rigorous demands of a pharmaceutical national quality control laboratory, supporting efficient, accurate, and compliant laboratory operations.
- EFDA MQCL must determine the data types and formats required for their workflow so that the IT team can configure the system properly to match the workflow sequence. EFDA-MQCL acquires the best selection that meets the needs by involving laboratory personnel in the initial stages of selection.
- QA manager should clearly define the laboratory objectives with respect to LIMS; this will inform QC analyst on how the system will look like during the post-implementation period. The functions in the Total Testing Process (TTP) that need to be configured to the LIMS must also be identified. QC analyst will prove to be very resourceful in this key exercise, since they understand the testing system extremely well. QC analyst shall ensure that the selected LIMS can address their needs.

Regulatory Compliance

- Ensure the LIMS meets FDA ***21 CFR Part 11*** regulations for electronic records and electronic signatures. Verify compliance with Good Manufacturing Practice and Good Laboratory Practice standards. Check if the LIMS supports processes needed for ISO 17025 accreditation.

Data Management and Integrity

- Robust security features, including user authentication, role-based access control, and data encryption. Comprehensive audit trails for tracking data changes and user activities. Built-in validation rules to ensure data accuracy and consistency.

Integration Capabilities

- Ability to integrate with a wide range of laboratory instruments for direct data capture. Seamless integration with Enterprise Resource Planning (ERP) and Manufacturing Execution Systems (MES).
- Availability of APIs for custom integrations and data exchange.

Functionality and Features

- Efficient sample tracking, from receipt to disposal, with barcode/RFID support.
- Management of test methods, protocols, and results.
- Tracking and managing laboratory reagents, chemicals, and supplies.
- Automation of SOPs and workflows.
- Customizable reporting tools and advanced analytics capabilities.

User Interface and Experience

- Intuitive and user-friendly interface.
- Ability to customize the interface and workflows to meet specific laboratory needs.
- Support for mobile devices to enable access from anywhere.

Scalability and Performance

- Ability to handle increasing data volume and user load without performance degradation.
- Fast and reliable performance with minimal downtime.

Support and Maintenance

- Availability of comprehensive support services from the vendor, including training, troubleshooting, and updates.
- Detailed documentation for users and administrators.

- Clear ***Service Level Agreements (SLAs)*** for system uptime, issue resolution, and support response times.

Deployment Options

- Availability of both cloud-based and on-premises deployment options.
- Robust data backup and disaster recovery mechanisms.

Cost Considerations

- Evaluation of initial setup costs, licensing fees, maintenance costs, and any additional costs for updates and customizations.
- Assessment of potential cost savings and efficiency gains.

Validation and Certification

- Vendor provided validation documentation and support for software validation processes.
- Relevant certifications (e.g., ISO 9001) held by the vendor.

User Feedback and References

- Feedback from current users regarding their experiences with the system.
- References from other pharmaceutical laboratories using the LIMS.

5.1 Roles and Responsibilities

- Responsibilities for LIMS are both administrative and technical. Roles must be very clear and defined for accountability purposes. These responsibilities must be captured in the relevant Standard Operating Procedure (SOP).

5.2 Stakeholders

- EFDA will be the main stakeholders in this venture. The QA and MQCL jointly shall have an oversight responsibility to ensure that implementation is done such that the system is qualified as efficient to ensure client issues are well addressed.

5.3 The LIMS Technical Working Group (TWG)

- The TWG will provide oversight in the implementation of LIMS nationwide. They have the responsibility to:

- Identify the potential users of LIMS
- Define roles and responsibilities especially for those who:
  - Access sample data and information.
  - Enter sample data and QC analysis results.
  - Change sample information and/or QC analysis results where applicable.
  - Authorize the release of QC analysis results and reports.
- Identify the major laboratory functions to be facilitated through LIMS.
- Define the LIMS budget.
- Identify equipment that will be integrated with LIMS.
- Determined software that will be suitable to be synchronized with the LIMS.
- Select the facilities where LIMS equipment will be installed.
- Define how LIMS will be maintained.
- Coordination of LIMS implementation activities
- Focused work at selected sites
- Provision of updates to relevant stakeholders
- Highlighting challenges that need to be addressed.
- Define elements of success.

- The TWG shall comprise of *QA, MQCL, LIMS administrators, Sample officers, and other pertinent persons.*

6 Technical Specifications

- The technical specifications of the URS should be detailed. The more information that can be provided to the vendor about the requirements of the laboratory, the more detailed and thorough the proposal will be.
- A detailed proposal will help the laboratory to make an informed decision concerning the purchase of a LIMS suited to the laboratory's particular needs.
- The technical specifications can be provided in an outline format. If possible, a table of compliance included in the URS can be of great assistance to the vendor in preparing its proposal and to the laboratory in evaluating proposals.

6.1 Sample Tracking and Management

- Sample tracking is a feature of every LIMS, but the way in which a sample is tracked by a LIMS is not the same for every vendor. Therefore, the laboratory should inform vendors exactly how the laboratory wants a sample to be tracked.
    - Should the LIMS be capable of differentiating between inhouse analyses and contract lab analyses?
- Data may include sample collector, collection date and time, sample receiver, received date and time, sample location code and address, and field data.
    - Does the laboratory want the LIMS to login samples automatically based on a predefined schedule?
    - Should the LIMS store static information about customers and sampling locations?
- **The proposal** should describe
    - The tracking of the sample through the laboratory.
    - What information is captured at log in?
    - How can data be retrieved?
    - What static information is stored for a sample location?
    - How samples could be scheduled.
    - Can scheduled samples be pre-logged in?
    - Can the sample information be modified?
    - How will the system handle scheduled samples that are not collected?

Sample Tracking

- Sample tracking shall begin with the sample request and track the sample through login, analysis scheduling, analysis, quality assurance, review and approval.
- An audit trail shall be maintained for each sample activity.
- Sample status will be readily retrieved.
- Provide a laboratory sample numbering format which is user configurable instead of by selecting from a fixed list of formats.
- Store unique field sample identification numbers that are configurable by the user and linked to the LIMS sample number.

- Integrate with portable field collection devices that utilize Windows Mobile Technology, allowing field collectors to collect field data and upload that data from any location that provides Internet access.
- Automatically calculate the sample hold times associated with the minimum time available for initiation of sample analysis based upon user input.
- Be capable of following the progress of samples throughout the analytical process and include integrated barcoding, sample login, chain of custody, price quoting and billing.
- Group samples into work lists, preparation batches, and QC batches by user definable selection criteria such as by batch, sample number, client, project, test, method, department,
- Provide a query function to retrieve sample information by work order, sample number, client, analysis, project test, department, date range, site, or other information for many functions throughout the LIMS.
- Have the ability to read a variety of bar code fonts and generate bar code labels representing laboratory and field sample identification numbers.
- Provide sample log-in and sample tracking capabilities capable of distinguishing samples being analyzed in-house versus those submitted to other governmental and/or contract laboratories. In-house analyses, as well as samples submitted to other laboratories, shall be tracked separately.
- The LIMS shall also enable the user to change the status of a sample from "in-house" to "contractual."
- Generate sample backlog reports identifying current sample workloads.
- Identify samples with completed client requested analysis and designate for samples and disposal

Manual Sample Login

- A manual sample login function shall record data including sample collector, sample location, sample date and time, sample type, sample receiver, sample received date and time, priority assignment, test(s) assigned, and sample splitting and field test data. This data shall be posted directly to the database. The login function shall be flexible enough to provide some degree of user customization, such as the addition of custom fields and custom sample identification formats, or to define sample types and categories.

Multiple Sample Login

- A multiple sample login function shall be provided. This function shall allow a batch of similar samples to be logged in one operation, assigning unique sample identifications to each sample, and duplicating common fields for each sample in the batch. Individual samples must then be modifiable at the user's discretion.

Auto Login

- The LIMS shall be able to automatically log samples according to a stored schedule.

Data entry and Storage

- Data entry functions shall perform immediate database updates. The user shall have the ability to retrieve test results, both manually and directly from the analytical instrumentation.
- Data shall be available for retrieval immediately after data entry. Data shall be transferred to an "archive" location. The end user shall have the ability to view this data without restoring the data into the "active" location.
- The system shall store and maintain records pertaining to the instrument's calibration data, as well as historical records on all instrumental repairs.
- Records pertaining to formal and informal training obtained by analysts shall be stored and maintained.
- Historical data from an Access database can be imported into the LIMS database.

Sampling site information

- Static information for sampling sites will be stored in the LIMS.
- The minimum data elements which will be stored are site ID., description, location, type and sample schedule.

Electronic import of historical results

- LIMS implementations benefit when electronic messaging is considered early in the design process. This messaging should include the ability to securely transfer result messages between data systems via national standard messaging formats, codes and terms. The LIMS

shall provide the capability to import historical data that is stored in electronic format, particularly ACCESS.

- Electronic data shall be imported directly from the analytical instrumentation, both manually and automatically by scanning directories. Instrument interfacing is required for the following instruments. Include instruments that will be interfaced here.
- The ability to create electronic messages is key to data exchange and to interoperability and the LIMS shall include data import and export capabilities.
- Electronic Data Deliverables should support the APHL EDD Requirements document attached to this document.

6.2 Sample Collection

- Barcode Sample Labels: The system shall permit printing sample identification labels with or without bar codes and reading/writing barcode labels **GTIN GS 128** style.
- The LIMS shall automatically log-in and schedule samples for a client/project in advance of the sample collection event. This feature shall address a variety of scheduling frequencies, including hourly, daily, weekly, biweekly, monthly, semi-annually and annually or via a special study

6.3 Sample Identification and Receiving

- One feature that many LIMS programs have is the ability to prioritize workloads.
- When a sample is received into the laboratory, it can be assigned a priority code. It should be specified in the URS if this is a desired feature. Samples can be logged into a LIMS in batches, individually, or both batches and individually.
- The URS should describe how the laboratory wants to log in samples.
    - Does the lab require the ability to associate comments with a sample?
    - Does the condition of the sample need to be recorded during sample log in?
    - Must the laboratory sample ID number follow a prescribed format?
- For many LIMS sample ID numbers follow the format of *yymm XXXX*, where *yy* is the year, *mm* is the month, and *XXXX* is a four-digit counter.
    - Not all LIMS offer flexibility in the numbering scheme.

Unique Sample Identification

- The LIMS shall automatically assign unique identification codes to each sample.
- In the case where a sample is split or subdivided, the LIMS shall assign and associate subsequent identification codes with the original sample.
- The LIMS shall allow user prioritizing of samples and their subsequent subparts and splits.

Sample Labels

- After uniquely identifying a sample, the LIMS shall be capable of providing labels for affixation to the sample container. The LIMS shall provide a standard format that can be duplicated and modified by an authorized user permitting various types of data to be retrieved from the database and incorporated on the label.
- The standard label format should include room for multiple fields besides the bar code and be user configurable.
- Modifications shall allow including special handling or safety procedures.
- The system shall provide the ability to specify the number of copies of the labels to generate, and shall provide a reprint option for single or multiple additional labels.

Bar Codes

- The LIMS shall be able to generate and read bar code **GTIN GS 128** style for identification, utilization on labels, chain of custody documents, and data entry purposes.

6.4 Sample Receiving

Receiving Details

- When samples arrive at the laboratory, the LIMS shall capture, at a minimum, the following receiving data items:
    - Date and time of receipt
    - Sample receiver
    - Location of sample
    - Date and time of sample collection
    - Sample collector
    - Unusual sample conditions
    - Test required (if not previously defined)
    - Tests requested

- Field test results
- Comments or ability for custom fields

Multiple Entry Methods

- The LIMS shall permit entry of the receiving details in multiple ways:
  - The LIMS shall be able to simultaneously log in and receive samples into the LIMS that are unexpected or nonroutine.
  - Samples of a particular type that arrive in batch shall be received in batch. It shall not be necessary for the user to reenter similar or repeat information for a series of samples.

Storage of Procedures and Tests

- The LIMS shall store information including tests required, lab sample preparation, sample holding time, and/or storage requirements with each sample type, such that the LIMS or the user can associate these tests, procedures and time limits with an incoming sample.

Associate Procedures and Tests with Samples

- Upon receipt of a sample, the LIMS shall associate appropriate preparation procedures and tests required for specific sample types.
- User shall be able to add or delete assigned tests.

Test Assignment Modifications

- Authorized users shall be able to modify tests or procedures assigned to logged in samples without modifying the standard procedures and test assignments.

Calculate Maximum Holding Time

- Based on sample types and tests required, the LIMS shall associate sample holding times with each sample based on its sampling time to produce maximum holding time/date(s).

6.5 Sample Scheduling

Routine Samples

- The LIMS shall be able to store sample collection locations and the frequency that various routine sample types are to be collected from each location.

Automatic Login

- The LIMS shall be able to log in routine samples automatically including the following:
    - Daily routine samples
    - Samples for specified days of the week
    - Monthly samples
    - Yearly samples

Automatic Test Scheduling

- For routine automatically logged samples, the LIMS shall be able to master schedule the test/analyses which will be required.
- The schedule shall include:
    - Daily routine samples
    - Specified days of the week
    - Monthly samples
    - Yearly samples
    - Quarterly
    - Semiannually

Sampling Site Information

- Static information for sampling sites will be stored in the LIMS.
- The minimum data elements that will be stored are site identification, description, location, and sample schedule.

6.6 Test/Analysis Administration

- Computers are ideal for performing routine calculations. When combined with the sample tracking and data entry functions of a LIMS they are ideal at calculating turnaround times, due dates, percentage recovery, and any other required calculation.
- If the calculation is properly set up, tested, and verified, this also ensures accurate calculations and decreases the potential for transcription errors.
    - Should the LIMS store calculation data about each test component?
    - Does the laboratory require that a single test contain multiple parameters?
    - How does the laboratory wish to enter analytical data?

- Results can be entered from one test performed on many samples, all results for many tests performed on one sample, or a combination of both ways.
    - Does the laboratory need to enter text data as well as numerical data?
    - Does data entry need to comply with good automated laboratory practice (GALP) regulations or electronic signature requirements?
    - Will results need to be entered, validated, and approved prior to reports being generated, or should reports be able to be generated prior to approval?
- Many LIMS allow the formation of test groups where many tests can be grouped together. This can be a great benefit if a number of tests are routinely assigned to samples.
- The LIMS should be able to mimic or improve upon the laboratory's current data entry procedures.

Standard Tests/Analyses per Sample Type

- Each test or analysis/type shall be uniquely identified with a code by the LIMS. The test identification code shall permit the association of multiple test components with that test code.
- The LIMS shall store data about each component such that the user can indicate, upon initial entry of the data, which components require computer performed mathematical computations.

Associate Developed Calculations with Tests

- In order to perform mathematical computations automatically, the LIMS shall permit the development and association of mathematical routines developed by authorized users for designated test codes.

Test Data Modification

- Modifications and deletions of test data by authorized users shall be permitted.

Test Result Entry

- Test results shall be entered in multiple formats.
- The LIMS shall be entered in multiple formats.
- The LIMS shall provide the entry of test results in the following formats, at a minimum:

- All results from one test performed on many samples.
- All results from many tests performed on one sample.
- All results from one test performed on one sample.

Special Result Values

- The LIMS shall be able to record special result values such as not detected, not measured, or null.
- The LIMS shall have the capability to correctly handle all special result values in mathematical computations.
- Users shall be able to define in advance how special result values will be handled in calculations.

User ID

- The LIMS shall be able to identify and capture data concerning which laboratory analyst performed the test, and which user entered the results

Instrument Interface

- The LIMS shall be capable of receiving results directly into its database from interfaced instruments.

6.7 Bench Sheets/Work Assignments

- A LIMS can produce bench sheets. If a laboratory desires this feature, the URS should specify what type of bench sheets are desired.
  - Should bench sheets and work assignments be able to be produced based on test, instrument, or analyst?
  - What information should be on the bench sheets? Should quality control samples be on the bench sheets?
- Only general requirements should be described: a detailed description for each bench sheet is not necessary.
- **The proposal** should be evaluated to determine if it fulfills the laboratory's requirements for the production of bench sheets. Several examples of bench sheets produced by the LIMS should be included.

Work Assignment Features

- The LIMS shall provide work assignment features for planning and scheduling the laboratory's workload.
- These features shall consider such data as:
    - Sample priority
    - Maximum valid holding time
    - Sample age
    - Due date

Work Assignment Reports

- A work assignment report, selectable by the following criteria, shall be provided:
    - Identical analysis type
    - Individual analyst
    - Individual workstation
    - Date

Bench Sheets

- The generation of the bench sheet shall be available upon request by a user or in a batch process.
- Single and/or group selection for reprinting shall be available upon request.
- The LIMS shall provide the capability to create an additional bench sheet for samples received after the original bench sheets were prepared.
- The ability to delete a sample or an analysis after it has been scheduled shall also be provided.

Bench Sheet Flexibility

- Bench sheet shall be created for one type of test and associate all samples assigned to that test to a bench sheet, as well as a bench sheet for one sample and all assigned tests.

Bench Sheet Contents

- Content of the bench sheet shall include, but not be limited to, the following characteristics:

- Specific analysis format (e.g., description of analysis, sample name, location, identity, sample date, analysis date, and name of analyst).
- Quality control samples: blanks, replicates and quality control spikes and standards.

6.8 Status Monitoring

- Status monitoring is how the LIMS monitors the status of a sample through the sample's life cycle.
- Desired features often include the ability to update a sample's status automatically.
    - What stages in a sample's life cycle does the laboratory wish to monitor: receipt, data entry, report generation, disposal?
    - Does the laboratory want its customers to have the ability to access their data via the Internet or customer call up? This information should be included in the URS.
- The methods for monitoring the status of a sample throughout its life cycle should be described. The status of the sample should be automatically updated based on events or transactions.

Sample Status

- The LIMS shall provide methods for monitoring sample status throughout the sample lifecycle. Sample status codes shall automatically be assigned and updated by the system based on events or transactions occurring.

Test Status

- The LIMS shall provide a method to monitor test and analysis status.
- The status of tests assigned to a specific sample identification code shall have a direct bearing on the status of the sample itself (e.g., a sample shall not be indicated as complete unless all assigned tests have a status of complete.)

Sample Status Codes

- The LIMS shall provide codes to monitor sample status for the following conditions, at a minimum:
    - Sample expected or logged, but not received
    - Sample received by the laboratory

- Sample has tests assigned that are in progress
- Sample has all assigned tests completed
- Sample results have been reviewed and verified
- Sample data has received formal approval from lab management
- A recollection of the sample has been ordered • Broken sample container
- Custom status codes defined by the laboratory

Test Status Codes and result management

- The LIMS shall provide codes to monitor test and analysis status for the following conditions, at a minimum:
  - Test is assigned to a bench sheet, and is in progress
  - Test is complete and results have been entered into LIMS
  - Test results have been reviewed
  - Test results have failed quality control
  - Test results have exceeded specified limits
  - A retest has been ordered for the same sample and test
  - Test results have associated text or limits violations

Comments

- The LIMS shall permit the entry of comments and/or coded comments, which may be inserted by users in place of, or in addition to, analytical result data.
- The LIMS shall permit the user, at the user's option, to enter an explanation in textual format to describe unusual conditions or circumstances.
- When test has been added to explain a test result, the LIMS shall indicate that associated text exists.

Calculations

- The system shall support calculations based on the results of multiple analyses and perform reasonableness checks on the computed results. The number of significant digits for calculations shall be user definable.

Results Limits

- Test data shall have associated results limits.

- The LIMS shall allow users to enter regulatory limits such as MDLs and MCLs and associate set of limits with each sampling location.
- Each analyte in a limit set shall have associated effective dates. These limits shall be used by the LIMS transaction programs to check results being entered and flag the user, during result entry, regarding adherence to the limits.

Multiple Limits Sets per Location

- The LIMS shall include the ability to specify multiple sets of limits for each sampling location.
- Each location shall have an associated primary limit set. All other limit sets at a location shall be considered as secondary limits.

Test Result Review

- The LIMS shall allow an authorized user to review test results.
- The review of test results shall be permitted in multiple fashions; by individual test code, by individual samples and a range of identification code(s), by analytical result date, and by bench sheet.
- Historical and Precision Level Comparisons
- For assistance in reviewing and approving test results, the LIMS shall allow the user to read historical results for sample locations and analyses.
- Precision levels of the analytical results based on Quality Control results shall also be available to the user.

Review Actions

- The review function shall allow the following actions:
- Reviewer indicates agreement or disagreement with the test result.
- Reviewer requires a retest, where a retest is defined as a multiple
- of the original performance of the test. The results from a retest shall be associated with the original sample identification and test code.

- Reviewer requests that the sample be collected from the same location again to rerun the test. This new sample will be associated with the original sample even if assigned a new sample number.
- Actions by the reviewer shall automatically update the status of samples and tests.

6.9 Sample Disposal

- The LIMS shall provide a means for users to know when samples may or should be disposed of.

6.10 Statistical Analysis and Quality Control

- A common quality control feature of many LIMS is the ability to associate sample analysis results with a set of quality control data for specific analytical batches. The laboratory should include in its URS the type of quality control samples the laboratory analyzes: blanks, sample duplicates, matrix spikes, matrix spike duplicates, surrogates, standards, or field blanks.
- Many LIMS can produce quality control charts but it should not be assumed that all LIMS provide this functionality. The URS should specify whether or not this is required.
    - The formatting of charts should be specified. Should the charts conform to EPA protocols?
    - What type of statistical analysis should the LIMS be able to perform? Are warning limits and control limits desired?
- The system shall track quality control, including sample replicates, matrix spikes, quality control check standards and blanks. Additionally, the system shall link all quality control data to the associated sample, test data and batch run. Quality control standards, check standards, surrogates, matrix spikes, spike duplicates, blanks, and sample replicates should all be handled by the LIMS. Input from the quality control manager and analysts should be solicited so that the LIMS requirements will include all of the laboratory's quality control needs.

Analysis and Graphics

- The LIMS shall include or provide an easy interface to a standard product for statistical analysis capability for historical trending and examination of LIMS data.

- Graphics capabilities shall also be provided for display and reporting of statistical information.

Graphics

- The user shall have the ability to create a variety of quality charts, plots, maps and trends generated from the graphics component based upon quality control data that has been entered into the system.

Interface Requirements

- If the statistical analysis and/or graphics functionality are not part of the standard LIMS, a seamless interface between a recommended product and the LIMS is preferred. If such an interface is not available, the proposer shall detail the procedure that will need to be followed by the user to use the statistical or graphical software in order to meet this requirement.

Sample Results with QC Sets

- The LIMS shall provide a means of calculating, storing, and retrieving Quality Assurance (QA) data such as blanks, spikes, duplicates, % recovered and quality control (QC) standards, and shall provide a method of associating sample analysis results with a set of quality control data for specific batches.

QC Calculations and Graphical Reports

- The system shall provide integration of simple calculations for the generation of sample analytical results. Besides, the system shall calculate quality control results and automatically flag all quality control data which is not within user defined quality control limits.
- The LIMS shall include the ability to generate precision and accuracy data by calculating standard deviation from replicate samples and QC standard.
- The LIMS shall construct and update QC charts using standard deviation, QC standard trending, data validation through predefined QC criteria, historical concentration ranges, and regulatory standards. Trending capabilities shall include the tracking of consistent bias.

6.11 Laboratory SOP

- The LIMS can store and manage the laboratory's standard operating procedures.
- It can document the history of test method revisions, including effective dates and retirement dates of the procedure.
- It can be used to maintain an inventory of the laboratory's standard operating procedures, each with its own unique document ID.
- The LIMS should also allow SOPs to be available online for analysts to view as they are working in the laboratory.

Data Sheets

- A data sheet (also called a bench sheet) is a form that is filled in as data are collected while a test is being run in the laboratory.
- Data sheets are kept as part of the official raw data records and usually include areas for sample identification, raw results, calculated results, blanks, standards, and comments on the test or samples.
- Data sheets will aid in the design of the test method entry screen used for the input of test data into the LIMS.

Log Books

- Log books may contain sample login information, test method, calculations, test results, instrument calibrations, and sample status.
- Examination of the log books may reveal another sample information that may need to be entered into a LIMS.

6.12 Reporting

- Manual and electronic data generated within the analytical quality control laboratory (chemical and physical testing) should be maintained and reported in a manner that ensures compliance with CGMP as well as with the FDA's measure of being attributable, legible, contemporaneous, original, and accurate (ALCOA). To comply with regulatory requirements, a firm must ensure that the original data generated is retained and/or that the record archived represents a true copy of the data

- Existing reports may include certificates of analysis, work schedules, customer test reports, daily sample analysis reports, quality control reports, and backlog reports, and lab production reports.
- Evaluation of current reports will give additional insight into the type of information that will need to be entered into LIMS, stored in, and retrieved from the LIMS.
- The examination of a sample analysis report may indicate that customer information needs to be stored in the LIMS.
- Test types and sample types will therefore need to be stored.
- Test results, both numerical and descriptive, must be able to be entered into the LIMS.
- All information must be able to be retrieved quickly.
- The LIMS shall:
    - Contain fully configurable reports.
    - Automatically report numeric results to the number of significant figures and decimal places as specified by the user.
    - Have the ability to enter text values into the result field.
    - Automatically report as "less than" any numerical data value which is less than the method detection limit specified by the user.

Automatic Reporting

- Perhaps one of the greatest time savers for the laboratory is the auto reporting function in many LIMS.
- Today auto reporting means more than a simple printout: it may involve automatic email notification for products that are out of specification, or automatic faxing of results that have been approved and validated.
- In addition to common reports, such as production, backlog, QC, and certificates of analysis, graphs can also be automatically generated.

Report Development

- Company A needs to generate regulatory reports, trend analyses, QA/AC charts, and graphically formatted reports for administrative planning purposes.

- The LIMS shall provide or recommend a third-party report development tool that is capable of integrating a wide variety of data types from multiple sources.
- Information from the LIMS database shall be available for report generation.
- This reporting tool shall include the following minimal capabilities:
    - **ODBC compliant**
    - **GUI development interface**
    - Calculations such as total, subtotal, subtraction, addition, multiplication, division, average, maximum, minimum, standard deviation, mean, median, and mode
    - Format options such a font size and type, page headers and footers, number of significant digits
    - Merging graphics, charts, and text into a single report
    - Retrieve and integrate data from Microsoft Access databases as well as the LIMS database
    - Create bar charts, trend lines, pie charts with retrieved data

Preprogrammed Reports

- The following set of preprogrammed LIMS reports shall be provided:
    - Samples received for a user specified time frame
    - Test results report, including comments
    - Work backlog report by sample status
    - Work backlog report by due date (sample aging)
    - Work backlog report by priority
    - Test results out of limits report
    - Quality control sample report

Workload Management Reports

- Workload management reports shall be providing to assist with interpretation for work assignment, staff load balancing and laboratory preference.
- The following types of reports shall be provided as part of the standard LIMS software:
    - Sample volume report (number of samples processed)
    - Test volume report (number of tests performed)
    - Turnaround time report from sample receipt to approval, summarized by analysis)

- User definable reports

6.13 Laboratory Instrument Interfaces

- Laboratories currently maintain data generated from laboratory instrument on the validated computer connected to the instrument, best practice is to maintain such data on a qualified server for increased security.
- Procedures should be established for the following:
  - Lifecycle management of the data collected, detailing the roles and responsibilities of the personnel operating these systems
  - Definition of quality oversight for the system administrator role, including access levels, roles, and periodic review of actions. To avoid any real or perceived conflict of interest, administrator privileges best be assigned to an individual who is not involved in laboratory activities. Also, any changes to administrator roles or privileges should be documented with Quality Unit oversight and approval.
  - Controls to prevent raw data from being overwritten, manipulated, or deleted without detection by enabling audit trails
  - Controls to verify detection (i.e., audit trail functionality) and accurate documentation to support any investigations (e.g., if a system audit trail has been turned off for any reason, it should be associated with proper justification)
  - Verification of the original, approved, validated state of the system
  - Systems to recover and review data in progress when an automated process has been interrupted (either manually or automatically)
  - Consistent names for files, file folders, and file paths of storage locations of electronic data
  - Demonstration that each step or event, such as processing of data to generate a result, is recorded at the time of the step or event and before the next step or event, such as reprocessing data
- Suggested controls to prevent and detect possible data integrity breaches include:
  - SOPs that require unique user identification and password; user types and permissions; registration and configuration of new systems; creation of folders to manage the hierarchies of data; and designation of who will perform

backups/restores and how often, who can create and adjust methods, who can optimize methods that can be changed, who can create data, who can approve and review data, who can determine what should be reviewed, and who can archive data when it is "completed"

- Protocol that restricts users from changing the system date and time
- Protocol that restricts permission to delete any kind of data to the responsible users who need it, e.g., restricting part of data archival procedures to only the independent administrator
- Procedure that allows only authorized personnel to access the application/operating system or install software updates and only under the appropriate change control by an authorized person independently approved by the Quality Unit to ensure system validation is preserved
- Security policies that configure and restrict access to data via the operating system to ensure maintenance of data integrity, including internet access
- Dedicated network or server for analytical systems (recommended)
- Automatic operating system updates must be disabled; only scheduled updates by IT personnel should be enabled
- When an analytical test run has been interrupted for any reason (e.g., power outage or equipment malfunction), appropriate documentation and a record of the event up to the point of interruption should be maintained, along with an assessment of the possible impact
- Mapping of end-to-end data process for the laboratory instrument to identify and mitigate data integrity risks and identify opportunities for future improvements
- Procedure requiring periodic data and audit trail reviews

- The URS should specify if the laboratory wishes to interface analytical instrumentation with the LIMS. Specific instruments and associated data handling software should be detailed and sample output files provided.
- The LIMS can keep track of instrumentation.
- Each equipment record can contain the following information: equipment name, equipment manufacturer's information, dates when equipment is received and placed in service, location of equipment, maintenance record, calibration dates and results. If it is required

that the instruments be able to directly parse their data to the LIMS, they will need to become part of the local area network.

- Each instrument will need to be identified by unique name or Internet Protocol (IP) address.

Electronic Instrument Interface

- Interface with the following instruments:
    - ***Shimadzu***
- Any instrument with an **RS232 port**
- Provide a method to identify each instrument uniquely.
- Able to receive and process analytical control sample results from instruments.

Unique Device ID

- In order for the LIMS to acquire test results from laboratory instruments, the LIMS shall provide a method to identify each device uniquely.

Direct Data Transfer

- The LIMS shall be able to receive and process analytical and quality control sample results directly from instruments that produce final results while the instrument is operational and without disrupting other LIMS users.

Data Processing

- After processing or data reduction, the LIMS shall be able to receive and process analytical and quality control sample results from PCs.
- The selected vendor shall provide the software required to transfer the data to the LIMS.

6.14 Computer Network

- The involvement of the Information Technology (IT) department is critical for successful LIMS implementation.
- IT usually maintains the LANs, WANs, file servers, and computers.
- At the beginning of the project it must be determined which LIMS items the IT department be responsible for supporting and which will be the responsibility of the LIMS administrator.

- All aspects of the LIMS should be discussed with the IT department, which should provide technical input and advice on infrastructural issues.
- The LIMS should describe
    - Whether the LIMS database and operating system are compatible or not with the operating system and databases already in place and supported by the IT department?
    - Who will maintain the LIMS server, perform backups, apply service packs, maintain system security, and maintain software licenses?
    - What will be the responsibilities of the IT department and of the LIMS administrator?
    - These roles must be clearly defined at the start of the project.

System Configuration

- A laboratory's URS should provide information on the type of computer network it uses:
- **The proposal** should describe
    - ***Novell, Windows NT, or another topology?***
    - Does the laboratory want a client/server system or a desktop system?
    - How are the computer clients configured?
    - Is the laboratory planning on buying new hardware based on the requirements of the LIMS or will the LIMS need to run on the laboratory's current hardware configuration?

Hardware/Software Configurations

- The vendor should indicate if their LIMS software would run on the laboratory's current computer system. If it cannot, technical specifications for required computer system components should be described in detail.

Security

- The software should include security measures, such as browser enabled user logins, that are properly challenged, mitigated, and verified. An additional layer of security should restrict access to verified user logins only.

- A major advantage of LIMS over a manual paper-based system is the multiple levels of security available to protect data integrity and allow laboratory personnel access to specific sections of the LIMS via passwords and to have a log of permissions and access.

System Security

- The task of assigning permission to access specific functionality to users of the LIMS usually lies with the database administrator.
- The database administrator has many responsibilities; including maintaining the static tables of the LIMS, assigning usernames and passwords, performing regular backups, and modifying report templates. If proper security is lacking in the LIMS, users may either accidentally or maliciously modify data.
- The more critical the information held in the LIMS, the tighter the security required.

Security features

- A good LIMS will have multiple levels of security: view only status; permissions for specific departments, but not others; view and approve permissions; or view, approve, and validate.
- A system for supervisory data review and approval of all analytical results shall be included. The network administrator shall have the ability to control user access to data.
- Changes made to any data field shall be audited and tracked by the system. Audit information shall include the name of the individual that made the change, date/time changed, original value, new value and reason the data was changed.
- Web reporting software shall support SSL (secure socket layer) to ensure data security and shall generate canned XML preliminary and final reports, provide a news editor, and provide one click capability to inactivate user accounts. PHL State IT will be responsible for obtaining SSL certification and installing it on the server.
- The application shall support a single sign-on process that includes the user's log-on id and password.
    - The fact that users must log into most LIMS with a user name and password identifies the time the user was logged onto the system and what results he or she entered. Like any system, it is only as secure as the users.

- If users share passwords, never logoff, or logon using coworkers' passwords, there is no good way to track changes or data entries.
- Stricter security procedures would then need to be implemented, including frequent changes to passwords and periodic reviews of user logs.

Network Security

- Networked environments provide another level of security and the network administrator typically assigns permissions to individuals or groups to access the network.
  - For example, network security should provide security for each user, directory, and file.
- Network securities rights typically include, read, write, delete, create new files, create new folders, and search capabilities.
- The examples provided here give the reader a good idea of how a LIMS can offer a laboratory increased assurance that high-quality data are generated.

6.15 Database management

- Data management describes the basic flow of analytical data from generation, review (verification and validation), and reporting. Laboratory staff and management are all integral parts of data management. The laboratory utilizes a LIMS database to perform data management activities.
- Periodic data backups, if applicable, should be implemented and archived. Archived data should be stored according to Quality Unit procedures. Archived data is generally stored offsite and should be checked for ease of data retrieval. Backup data should be more readily accessible

Data entry restriction

- A reliable LIMS function is checking information entered into the LIMS to ensure that it is of the correct format and field size. LIMS administrator creates and/or modifies approved laboratory staff access to LIMS; creates and modifies LIMS methods, data templates and transfers, and data reports; and is able to modify data in LIMS.
- All users must be authorized by management to receive program access to LIMS. Different privileges are given to authorized users depending on need. Access may include:

- Read-only
- Data entry
- Addition of test methods
- Modification of preliminary data
- Data transfer
- Data reporting
- Data upload
- Data system administration

Enhancing data quality with LIMS

- There can also be automatic limit checking (e.g., the LIMS will not allow users to enter a pH of 25) and there can be validity checking (e.g., you cannot analyze a sample before the manufacture date).

Range or limit checking

- Built-in upper and lower warning limits can automatically alert a user that data is outside an upper or lower warning range or a hard limit (e.g., a pH of 18).
- These ranges are usually established by the user, for test ranges, client specifications, or user definition.

Limit to List

- The utilization of pick lists greatly reduces spelling errors and forces consistency in test names and other common pulldown list items.
    - For example, for a particular matrix, it will only display tests that can be performed on that particular matrix.
- The user's choices will be limited to the items on the pulldown list, and a ''hot'' lookup is often employed so that the user need just begin typing the item and the list will jump to that item.
- Pick lists are extremely useful for avoiding data entry errors, especially typographical errors. Another feature that is also helpful, but not as critical as limit to list, is the ability to prompt the user to perform a function.

- For example, after a user audits a result record, and before they close the screen, they receive a message reading ‘‘you must provide a reason for the change before you can close.’’
- Another feature that helps to decrease data entry errors is the use of barcodes, which can contain information about the sample, avoids transcription errors and saves keystrokes in entering information.
- The vendor should be informed if data will need to be transferred from another LIMS or other database into the new LIMS.
- The LIMS should describe
    - Does the laboratory have a preferred database for the LIMS such as Oracle, Microsoft SQL server, or Access?
    - How many concurrent users are expected to use the system? That determines the system’s software licensing requirements.
    - If the lab wishes to import or export data from the LIMS, it should be specified in the URS.
    - The database management tools available in the LIMS, the licensing requirements, and the ability to export or import data.

6.16 Chemical inventory

- The system shall maintain an inventory of all chemicals used in the environmental laboratory, including but not limited to chemical name, expiration date, location of storage and vendor used for procurement. A chemical inventory module is available with most LIMS.
    - The URS should specify whether or not this should be included.
- The LIMS should describe
    - Should the LIMS store vendor information and pricing?
    - Should lab personnel be notified when to order supplies?
    - Should the LIMS store MSDS information?

6.17 Accounting functions

- ***The URS should specify whether or not this should be included.***

- Many LIMS systems provide basic accounting functions, such as costs per sample, quotation generation, and invoicing. Some LIMS interface with third party software for accounting purposes.
- Accounting functions may be optional for some LIMS and the function can be turned off if desired, but other LIMS systems require a sample to be ‘‘invoiced’’ in order for a report to be generated.
- The accounting department’s needs must be solicited. Many LIMS can track the costs associated with each test.
- Pricing can be programmed into the LIMS so that it is uniquely tailored for each customer or project. Information about each sample can be exported to accounting software for invoicing purposes.
- The LIMS should describe
    - If accounting features are included with the LIMS package.
    - Will the LIMS need to interface with accounting software?
    - Should the LIMS have the ability to invoice customers?
    - Can cost be assigned to individual tests or group of tests?
    - If accounting features are included, must a sample be ‘‘invoiced’’ in order to archive a sample?
    - Will the LIMS interface with other accounting software packages?

6.18 Documentation

- The vendor should provide all documentation for the LIMS application. This should include installation instructions, an administrator’s manual, an end user’s manual, and documentation on instrument interfaces. The source code should be provided or held in escrow in case the LIMS vendor should go out
- Company A shall have placed the LIMS source code in escrow.
- The Proposer shall provide complete hard and soft documentation for the LIMS application and the instrument interfaces. This shall include installation instructions, system administration and maintenance, technical reference and users’ manuals and any other manuals relevant to the selected LIMS application.
- A simple step-by-step user’s manual shall be provided for the end users.

6.19 Online queries

- A laboratory wants to be able to retrieve logically related data quickly and easily, in an interactive environment, without the need for detailed understanding of data storage and programming techniques.
    - In what ways does the laboratory wish to retrieve data: by sample number, location code, and test?
    - Does the laboratory staff want the results displayed on the workstation screen, sent to a printer, saved as an ASCII file, or exported to another program?

Ad Hoc Queries

- End-users shall be able to retrieve logically related data, quickly and easily, in an interactive environment, without the need for a detailed understanding of data storage and programming techniques.

Multiple query criteria

- The LIMS data inquiry facility shall provide efficient retrieval of sample data based on sample identification code, location, analyst name, date received, workstation or device, test, analyte, result values, sample type, and sample status.

Structured query language tools

- End-user tools that use an SQL interface shall be provided. The LIMS shall provide the user with a query facility which supports nested query, table joins, and outerjoin functionality.

Standard queries

- The LIMS shall provide standard queries for, at least, a specific sample's associated data, all results for a specific sample collection location, status of samples, status of tests being performed, and all administrative or static data.

Multiple output options

- The query function shall be capable of displaying query results on the user's workstation screen, sending them to a printer or saving them as an ASCII file. Saved queries shall be exportable through, or accessible from, ODBC drivers.

6.20 Training

- The type and frequency of desired training should be included in the URS.
    - Should training be provided onsite or at vendor training centers?
    - How many system administrators and how many end-users will require training? Will follow-up training be required?
- The URS should specify that a course syllabus for all vendor provided training be included in the vendor's proposal.
- The selected Proposer shall train the laboratory and systems personnel in the use of all LIMS application software. Initial training shall be conducted onsite at Company A. Follow-up training can be provided onsite or at regional training centers.
- The selected Proposer shall provide all instructors and instructional material including trainees' workbooks, instructor guides, training aids, equipment, and technical manuals.
- The selected Proposer shall coordinate with Company A regarding use of facilities if courses are to be held onsite.
- Equipment and software that are provided as part of this contract may be utilized for training, provided they are not adversely affected. Any equipment or software modified for training by the Proposer shall be restored to its original condition.
- Courses that include general programming elements shall provide instruction such that the attending student will be capable of programming related software applications and/or modifications without guidance, or with only minimal supervision. This requirement applies only to the software supplied by the LIMS Proposer.
- At a minimum, required courses are as follows:
    - ***End-user Training***: Provide training sessions onsite that instruct 10 end-users in the overall use and operation of the LIMS application software.
    - ***System Administration Training***–Provide training onsite for two (2) owner designated personnel who will act as system administrators for the LIMS computer configuration and applications.
    - The training shall include LIMS administration tasks, software management functions, and computer security.
    - The training shall also include complete system backup and reload procedures, file management utilities, and system generator procedures.

- ***The proposal*** should include details on the training provided by the LIMS vendor.
    - The vendor should be able to provide training on all items it supplies.
    - Initial training should be onsite, with follow-up training available at the vendor's location.
    - A course outline for all training courses should be included in the proposal

7 Table of Compliance to Specifications

- Implementing a robust and compliant LIMS tailored to the needs of the any NQCL will ensure efficient laboratory operations, adherence to international standards, and improved data integrity and security.
- The detailed technical requirements outlined provide a comprehensive framework for selecting and implementing a LIMS that meets these goals and supports the laboratory's mission of ensuring public health and safety.

7.1 System Configuration

1. Network

The LIMS shall be installed on the Ethernet network, with the **Novell 3.12 or 4.x network** operating system.

2. Database Server

Company A will supply and install a database server for the LIMS application. The LIMS shall run on this server, configured in client/ server mode.

The server will meet the following general specifications:

- Intel 200 MHz Pentium with 256 MB RAM
- Windows NT Server
- A mirrored 4 MB wide **SCSI hard drive**
- CD ROM drive

3.Personal Computers

The client workstations are 133 MHz Pentiums with 64 MB RAM that will be dedicated to the LIMS

System Configuration	REF	C	DC	CWM	Remark
The LIMS shall be compatible and run on an Ethernet network with the Novel Network 4.x network operating system	**1**				**IT**
The system shall run on the Company A Server as previously described	**2**				**IT**
The system must be an ACCESS or SQL Based client/server application	**2**				**IT**
The system's client software will run on 133 MHz Pentiums with 64MB RAM	**3**				**IT**

REF: Reference, C: Comply, DC: Do Not Comply, CWM: Comply With Modification

7.2 System Management

1. ***Licensed users***

   The LIMS shall be licensed for 8 concurrent users not counting the interfaced instruments. Up to 10 workstations shall have access to the LIMS.

2. ***Compatibility***

   The LIMS shall run on a server platform and an operating system compatible with the existing **Novell NetWare 4.x.**

3. ***System Management Tools***

   The LIMS shall provide system management tools to permit safe, secure management of the LIMS application.

   These tools shall include application security, data audit trail, database backup/recovery, data archival/restoration and interoperatability with SQL based and **ASCII** based applications.

4. ***Security***

   The LIMS system shall provide security features to ensure that only authorized individuals enter, view and modify data.

   Access levels shall be definable to restrict use of system level functions (such as user authorization), and to provide data access levels to restrict the use of data entry, data approval, data retrieval, data modification, database structure creation or modification functions.

5. ***Data Archiving and Purging***

The LIMS shall provide a means to archive and purge (delete) data at the request of the system administrator, or automatically after a specified period of time.

- Archiving is removing the data from the active database and storing it in a retrievable form elsewhere.
- Archiving must include user selectable parameters. These parameters shall include collection and approval date ranges, sample type, location, and test.
- The purge utility must also include user selectable parameters. These parameters shall include collection and approval date ranges, sampling point and sample type.

6. Static Information

The LIMS shall maintain static administrative information such as, but not limited to, procedures, safety information, and project information.

Authorized users shall be able to query, add, modify, and delete this information.

System Management	**REF**	**C**	**DC**	**CWM**	**Remark**
The LIMS shall be licensed for 8 concurrent users not counting the interfaced instruments. Up to 10 workstations shall have access to the LIMS	**1**				
The LIMS shall run on a server platform and an operating system compatible with a Novell Netware 3.12 and 4.x.	**2**				**IT**
Provide system management tools as defined in the Scope of Work Technical Specifications					
Provide owner definable security by user, user group, function	**4**				
Access levels shall:					
Restrict user of system level functions (such as user authorization)	**4**				
Restrict the use of data entry, data approval, data retrieval, data modification, database structure creation or modification functions	**4**				
Provide a means to archive data:					
Include collection and approval data ranges, sample type, location, and test					
At the request of system administrator	**5**				

Automatically after a specified period of time	**5**				
Include userselectable parameters	**5**				
Provide a means to purge data:					
At request of system administrator	**5**				
Parameters shall include collection and approval date ranges, sampling point and sampling type	**5**				
Automatically after a specified period of time	**5**				
Includes userselectable parameters	**5**				
Maintain static administrative or business rules information	**6**				
Authorized users shall be able to query, add/modify, and delete this administrative and rule information	**6**				

REF: Reference, C: Comply, DC: Do Not Comply, CWM: Comply With Modification

7.3 Database Management

1. Relational Database Management System

The LIMS shall provide a **relational database management system (RDBMS)**for information storage and retrieval.

- The LIMS RDBMS shall be available with a full use license, providing not only access to the LIMS application, but also application development tools, a data dictionary, a data query utility, and a report writer. The preferred databases are **ACCESS or SQL.** Oracle systems will not be considered.
- The RDBMS shall be licensed for eight concurrent runtime users. The database development tools shall be licensed for two users. The report writer tools shall allow development by five concurrent users.
    - The RDBMS shall support client/server architecture.
    - The RDBMS shall support parallel processing.
    - The RDBMS shall be able to support data spanning multiple physical disks.
    - The RDBMS shall run on multiple server operating systems, such as Windows NT or Novell NetWare.

2. Transaction Journal Utility

A transaction journal utility shall provide database reconstruction in case of system failure. This facility shall restrict the possible loss of data to the database transactions in progress when the system fails. Proposer must provide written instructions for reconstruction.

3. Graphical User Interface

The LIMS user interface and all interactive database management tools shall be a simple to use graphical user interface (GUI).

4. Data Export

The Database System shall be able to extract and convert data elements into an ASCII format for use outside of the LIMS application environment.

The following file formats are desired or required, as indicated:

- **ASCII: Required**
- **EXCEL: Required**
- **Lotus: Desired**

5. Data Import

The Database system shall be able to import an ASCII data file, convert it as needed, and store the data in the LIMS database management system.

6. Interoperability

The database system shall be ODBC compliant. It will allow data exchange with other ANSI SQL, ODBC compliant database systems, including Microsoft Access.

Compliance will also enable the database to interface with ODBC compliant word processing, statistical analysis and spreadsheet software for producing reports, letters, memoranda and other documents.

7. Data Dictionary

The data dictionary shall control the definition and manipulation of data, and facilitate changes to data structures.

Database Management	**REF**	**C**	**DC**	**CWM**	**Remark**
Provide a relational database management system (either ACCESSS or SQL) for information storage and retrieval	**1**				**IT**

The LIMS RDBMS shall be available with full use license, providing not only access to the LIMS application, but also:					
• Application development tools	**1**				
• A data dictionary	**1**				
• A data query utility	**1**				
• A report writer	**1**				
The RDBMS shall be licensed for 18 users	**1**				
Database development tools shall be licensed for two users	**1**				
The RDBMS shall support client/server architecture	**1**				
The RDBMS shall support parallel processing	**1**				
The RDBMS shall support data spanning multiple physical disks	**1**				
A transaction journal utility shall provide database reconstruction in case of system failure	**2**				
Interactive database management tools shall be a GUI interface	**3**				
The RDBMS shall be able to export data into the following formats:					
• ASCII	**4**				
• Excel	**4**				
• Lotus	**4**				
RDBMS shall be able to import an ASCII data file	**5**				
Historical data from an ACCESS database can be imported into the LIMS database	**5**				
The database shall be ODBC compliant and will allow exchange of data with other ANSI SQL, ODBC compliant database systems such as MS Access	**6**				**IT**
The database dictionary shall control the definition and manipulation of data and facilitate changes to data structures.	**7**				

REF: Reference, C: Comply, DC: Do Not Comply, CWM: Comply With Modification

7.4 Sample Management and Tracking

1. Sample Tracking

- Sample tracking shall begin with the sample request and track the sample through login, analysis scheduling, analysis, quality assurance, review and approval.
- An audit trail shall be maintained for each sample activity. Sample status will be readily retrieved.
- The system track status and workflow of the accession throughout the laboratory lifecycle, from submission to final analysis, including receiving, testing, and test result reporting

2. Manual Sample Login

A manual sample login function shall record data including sample collector, sample location, sample date and time, sample type, sample receiver, sample received date and time, priority assignment, test(s) assigned, and sample splitting and field test data. This data shall be posted directly to the database.

The login function shall be flexible enough to provide some degree of user customization, such as the addition of custom fields and custom sample identification formats, or to define sample types and categories.

3.Multiple Sample Login

A multiple sample login function shall be provided. This function shall allow a batch of similar samples to be logged in one operation, assigning unique sample identifications to each sample, and duplicating common fields for each sample in the batch. Individual samples must then be modifiable at the user's discretion.

4. Auto Login

The LIMS shall be able to automatically log samples according to a stored schedule. A LIMS generated number or other unique identification number (barcode) must be given to all samples prior to analysis or preparation. Pertinent information from the COC is entered into LIMS during the login process.

5. Data Entry

Data entry functions shall perform immediate database updates. Data shall be available for retrieval immediately after data entry. Historical data from an Access database can be imported into the LIMS database.

6. ***Sampling Site Information***

Static information for sampling sites will be stored in the LIMS.

The minimum data elements which will be stored are site id., description, location, type and sample schedule.

7. ***Electronic Import of Historical Results***

The LIMS shall provide the capability to import historical data that is stored in electronic format, particularly ACCESS.

Sample Management And Tracking	**REF**	**C**	**NC**	**CWM**	**Remark**
Sample tracking shall track the sample from login, analysis, quality assurance, review and approval. Sample status will be readily retrieved.	**1**				
A manual sample login function shall record data including					
• Sample collector	**2**				
• Sample collection date/time	**2**				
• Sample receiver	**2**				
• Sample received date/time	**2**				
• Sample location code	**2**				
• Sample location	**2**				
• Tests assigned	**2**				
• Priority assignment	**2**				
• Field analysis data such as temperature, pH, chlorine residual	**2**				
The login function shall allow user customization:					
The addition of custom fields	**2**				
Custom sample identification formats	**2**				
Provide a function to login multiple similar samples in one operation. Individual samples must then be able to be modified at the users discretion	**3**				
The LIMS shall be able to login samples automatically according to a stored schedule	**4**				
Data shall be available for retrieval immediately after data entry	**5**				

Data entry functions perform immediate database updates or inserts	**5**				
Store static information for sampling sites:					
• Site ID	**6**				
• Description	**6**				
• Location	**6**				
• Sample type	**6**				
Provide the capability to importhistorical test result data stored in an ACCESS database	**7**				

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7.5 Sample Scheduling

1. ***Routine Samples***

   The LIMS shall be able to store sample collection locations and the frequency that various routine sample types are to be collected from each location.

2. ***Automatic Login***

   The LIMS shall be able to log in routine samples automatically including the following:

   - Daily routine samples
   - Samples for specified days of the week
   - Monthly samples
   - Yearly samples

3. ***Automatic Test Scheduling***

   For routine automatically logged samples, the LIMS shall be able to master schedule the test/analyses which will be required. The schedule shall include:

   - Daily routine samples
   - Specified days of the week
   - Monthly samples
   - Yearly samples
   - Quarterly
   - Semiannually

4. ***Sampling Site Information***

   Static information for sampling sites will be stored in the LIMS.

The minimum data elements that will be stored are site identification, description, location, and sample schedule.

Sample Scheduling	REF	C	NC	CWM	Remark
Store locations for routine sample collection	**1**				
Be able to login routine samples automatically including the following:					
• Daily routine samples	**2**				
• Samples for specified days of the week	**2**				
• Monthly samples	**2**				
• Yearly samples	**2**				
For routine automatically logged samples, be able to master schedule the required tests including:					
• Daily routine samples	**3**				
• Specified days of the week	**3**				
• Monthly samples	**3**				
• Yearly samples	**3**				
• Quarterly samples	**3**				
• Semiannual samples	**3**				
Status information for sampling sites shall be stored in the LIMS	**4**				

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7.6 Sample Collection

Barcode Sample Labels: The system shall permit printing sample identification labels with or without bar codes and reading/writing barcode labels according to **GTIN GS 128.**

Sample Collection	REF	C	NC	CWM	Remark
The system shall permit printing sample identification labels with or without bar codes and reading/writing **GTIN GS 128.**	**1**				

REF: Reference, C: Comply, DC: Do Not Comply, CWM: Comply With Modification

7.7 Sample Identification

1. Unique Sample Identification

The LIMS shall automatically assign unique identification codes to each sample. In the case where a sample is split or subdivided, the LIMS shall assign and associate subsequent identification codes with the original sample.

2. Priorities

The LIMS shall allow user prioritizing of samples and their subsequent subparts and splits.

3. Sample Labels

After uniquely identifying a sample, the LIMS shall be capable of providing labels for affixation to the sample container.

The LIMS shall provide a standard format that can be duplicated and modified by an authorized user permitting various types of data to be retrieved from the database and incorporated on the label.

The standard label format should include room for multiple fields besides the bar code and be user configurable. Modifications shall allow including special handling or safety procedures.

The system shall provide the ability to specify the number of copies of the labels to generate, and shall provide a reprint option for single or multiple additional labels.

4. Bar Codes

The LIMS shall be able to generate and read bar code based on **GTIN** style for identification, utilization on labels, chain of custody documents, and data entry purposes.

Sample Identification	**REF**	**C**	**NC**	**CWM**	**Remark**
Ability to assign unique identification codes to each sample	**1**				
Able to prioritize samples	**2**				
Can provide user definable sample labels	**3**				
Provide the ability to specify the number of labels needed to allow a reprint option	**3**				
Able to generate and read barcode style 128 codes for identification, utilization on labels, chainofcustody forms	**4**				

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7.8 Sample Receiving

1. Receiving Details

When samples arrive at the laboratory, the LIMS shall capture, at a minimum, the following receiving data items:

- Date and time of receipt
- Sample receiver
- Location of sample
- Date and time of sample collection
- Sample collector
- Unusual sample conditions
- Test required (if not previously defined)
- Tests requested
- Field test results
- Comments or ability for custom fields

2. Multiple Entry Methods

The LIMS shall permit entry of the receiving details in multiple ways:

- The LIMS shall be able to simultaneously log in and receive samples into the LIMS that are unexpected or nonroutine.
- Samples of a particular type that arrive in batch shall be received in batch. It shall not be necessary for the user to reenter similar or repeat information for a series of samples.

3. Storage of Procedures and Tests

The LIMS shall store information including tests required, lab sample preparation, sample holding time, and/or storage requirements with each sample type, such that the LIMS or the user can associate these tests, procedures and time limits with an incoming sample.

4. Associate Procedures and Tests with Samples

Upon receipt of a sample, the LIMS shall associate appropriate preparation procedures and tests required for specific sample types. User shall be able to add or delete assigned tests.

5. Test Assignment Modifications

Authorized users shall be able to modify tests or procedures assigned to logged in samples without modifying the standard procedures and test assignments.

6. Calculate Maximum Holding Time

Based on sample types and tests required, the LIMS shall associate sample holding times with each sample based on its sampling time to produce maximum holding time/date(s).

Sample Receiving	REF	C	DC	CWM	Remark
The LIMS shall be able to capture the following information at sample login:					
• Sample collector	**1**				
• Sample collection date/time	**1**				
• Sample receiver	**1**				
• Sample received date/time	**1**				
• Sample location code	**1**				
• Sample location	**1**				
• Tests assigned	**1**				
• Priority assignment	**1**				
• Field analysis data such as temperature, pH, chlorine residual	**1**				
• Comments or capability for custom fields	**1**				
The LIMS shall permit entry of receiving details in multiple ways:					
Simultaneously login and receive unexpected or nonroutine samples	**2**				
Samples of a particular type that arrive in batch shall be received in batch	**2**				
Store information with each sample type including:					
Tests required	**3**				
Lab sample preparation procedures	**3**				
Holding times	**3**				
Sample storage/preservation requirements	**3**				
Ability to add or delete assigned tests	**4**				
Associate procedures and tests with samples	**4**				
Authorized users shall be able to modify tests or procedures assigned to samples without modifying the standard procedures and test assignments	**5**				

Associate sample holding times with each sample based on its sampling time to produce maximum holding time/date(s)	**6**				

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7.9 Test/Analysis Administration

1. ***Standard Tests/Analyses per Sample Type***

   Each test or analysis/type shall be uniquely identified with a code by the LIMS.

   The test identification code shall permit the association of multiple test components with that test code.

   The LIMS shall store data about each component such that the user can indicate, upon initial entry of the data, which components require computer performed mathematical computations.

2. ***Associate Developed Calculations with Tests***

   In order to perform mathematical computations automatically, the LIMS shall permit the development and association of mathematical routines developed by authorized users for designated test codes.

3. ***Test Data Modification***

   Modifications and deletions of test data by authorized users shall be permitted.

4. ***Test Result Entry***

   Test results shall be entered in multiple formats.

   The LIMS shall be entered in multiple formats.

   The LIMS shall provide the entry of test results in the following formats, at a minimum:

   - All results from one test performed on many samples.
   - All results from many tests performed on one sample.
   - All results from one test performed on one sample.

5. ***Special Result Values***

   The LIMS shall be able to record special result values such as not detected, not measured, or null.

   The LIMS shall have the capability to correctly handle all special result values in mathematical computations.

Users shall be able to define in advance how special result values will be handled in calculations.

6. ***User ID***

   The LIMS shall be able to identify and capture data concerning which laboratory analyst performed the test, and which user entered the results

7. ***Instrument Interface***

   The LIMS shall be capable of receiving results directly into its database from interfaced instruments.

Test/Analysis Administration	**REF**	**C**	**DC**	**CWM**	**Remark**
Uniquely identify with a code each test or analysis type	**1**				
Permit the association of multiple test components with each test identification code	**1**				
Store calculation data about each test component	**1**				
Permit the development and association of mathematical routines for designated test codes and components	**2**				
Permit modification of test data by authorized user with audit trail	**3**				
Provide the entry of test results in the following formats:					
All results from one test performed on many samples	**4**				
All results from many tests performed on one sample	**4**				
All results from one test performed on one sample	**4**				
Able to record special result values such as not detected, , or null	**5**				
Correctly handle all special result values in mathematical computations	**5**				
Users shall be able to define in advance how special result values are handled in calculations	**5**				
Able to identify test analyst	**6**				
Ability to identify user who entered results	**6**				
Ability to receive results directly into the LIMS database from interfaced equipment	**7**				

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7.10 Bench Sheet/Work Assignment

1. Work Assignment Features

The LIMS shall provide work assignment features for planning and scheduling the laboratory's workload.

These features shall take into account such data as:

- Sample priority
- Maximum valid holding time
- Sample age
- Due date

2. Work Assignment Reports

A work assignment report, selectable by the following criteria, shall be provided:

- Identical analysis type
- Individual analyst
- Individual workstation
- Date

3. Bench Sheets

The generation of the bench sheet shall be available upon request by a user or in a batch process. Single and/or group selection for reprinting shall be available upon request.

The LIMS shall provide the capability to create an additional bench sheet for samples received after the original bench sheets were prepared.

The ability to delete a sample or an analysis after it has been scheduled shall also be provided.

4. Bench Sheet Flexibility

Bench sheet shall be created for one type of test and associate all samples assigned to that test to a bench sheet, as well as a bench sheet for one sample and all assigned tests.

5. Bench Sheet Contents

Content of the bench sheet shall include, but not be limited to, the following characteristics:

- Specific analysis format (e.g., description of analysis, sample name, location, identity, sample date, analysis date, and name of analyst).
- Quality control samples: blanks, replicates and quality control spikes and standards.

Bench Sheet/Work Assignment	REF	C	DC	CWM	Remark
Provide work assignments features for planning and scheduling the laboratory workload which consider:					
• Sample priority	**1**				
• Maximum holding time/date	**1**				
• Sample age	**1**				
• Due date	**1**				
Provide work assignment report, selectable by the following criteria:					
• Analysis type	**2**				
• Analyst	**2**				
• Workstation	**2**				
• Date	**2**				
Able to generate a bench sheet upon request	**3**				
Able to reprint single and/or group selection of bench sheets upon request	**3**				
Able to create additional bench sheets for samples received after the original bench sheets were prepared	**3**				
Able to delete a sample or an analysis after it has been scheduled	**3**				
Create bench sheets for one type of test and associate all samples assigned to that test to a bench sheet	**4**				
Create bench sheets for one sample and all assigned tests	**4**				
Bench sheet contents shall include:					
• Description of analysis	**5**				
• Sample name	**5**				
• Location	**5**				
• Identity	**5**				
• Sample date	**5**				
• Analysis date	**5**				
• Name of analyst	**5**				
• Quality control samples	**5**				

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7.11 Status Monitoring

1. Sample Status

The LIMS shall provide methods for monitoring sample status throughout the sample lifecycle. Sample status codes shall automatically be assigned and updated by the system based on events or transactions occurring. The LIMS number and/or barcode assigned to a sample must appear on all associated documentation, such as the COC, sample report form, the sample folder, LIMS, and any laboratory worksheet associated with the sample.

2. Test Status

The LIMS shall provide a method to monitor test and analysis status. The status of tests assigned to a specific sample identification code shall have a direct bearing on the status of the sample itself (e.g., a sample shall not be indicated as complete unless all assigned tests have a status of complete.)

3. Sample Status Codes

The LIMS shall provide codes to monitor sample status for the following conditions

- Sample expected or logged, but not received
- Sample received by the laboratory
- Sample has tests assigned that are in progress
- Sample has all assigned tests completed
- Sample results have been reviewed and verified
- Sample data has received formal approval from lab management
- A recollection of the sample has been ordered • Broken sample container
- Custom status codes defined by the laboratory

4. Test Status Codes

The LIMS shall provide codes to monitor test and analysis status for the following conditions, at a minimum:

- Test is assigned to a bench sheet, and is in progress
- Test is complete and results have been entered into LIMS
- Test results have been reviewed
- Test results have failed quality control
- Test results have exceeded specified limits
- A retest has been ordered for the same sample and test

- Test results have associated text or limits violations

5. Sample Disposal

The LIMS shall provide a means for users to know when samples may or should be disposed of.

Status Monitoring	REF	C	DC	CWM	Remark
Provide methods for monitoring sample status throughout the sample lifecycle login:	**1**				
Automatic update of sample status based on events or transactions	**1**				
Provide a method to monitor test and analysis data	**2**				
Provide codes to monitor sample status for the following conditions:					
• Sample received by the laboratory	**3**				
• Samples expected or logged by not received	**3**				
• Sample has tests assigned that are in progress	**3**				
• All assigned tests are completed	**3**				
• Sample results have been reviewed and verified	**3**				
• A retest has been ordered	**3**				
• Broken sample container	**3**				
Provide codes to monitor test and analysis status for the following conditions:					
• Test is complete	**4**				
• Test results have failed quality control	**4**				
• Test results exceed specified limits	**4**				
• Test results have associated text or limits violations	**4**				
• Test is assigned to a bench sheet and is in progress	**4**				
• Test results have been reviewed	**4**				
• A retest has been ordered for the same sample and test	**4**				
Provide a means for informing when a sample may be disposed of	**5**				

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7.12 Test Result Management

1. Comments

The LIMS shall permit the entry of comments and/or coded comments, which may be inserted by users in place of, or in addition to, analytical result data.

The LIMS shall permit the user, at the user's option, to enter an explanation in textual format to describe unusual conditions or circumstances.

When test has been added to explain a test result, the LIMS shall indicate that associated text exists.

2. Calculations

The system shall support calculations based on the results of multiple analyses and perform reasonableness checks on the computed results. The number of significant digits for calculations shall be user definable.

3. Results Limits

Test data shall have associated results limits. The LIMS shall allow users to enter regulatory limits such as **MDLs and MCLs** and associate set of limits with each sampling location. Each analyte in a limit set shall have associated effective dates.

These limits shall be used by the LIMS transaction programs to check results being entered and flag the user, during result entry, regarding adherence to the limits.

4. Multiple Limits Sets per Location

The LIMS shall include the ability to specify multiple sets of limits for each sampling location. Each location shall have an associated primary limit set. All other limit sets at a location shall be considered as secondary limits.

5. Test Result Review

The LIMS shall allow an authorized user to review test results.

The review of test results shall be permitted in multiple fashions; by individual test code, by individual samples and a range of identification code(s), by analytical result date, and by bench sheet.

6. Historical and Precision Level Comparisons

For assistance in reviewing and approving test results, the LIMS shall allow the user to read historical results for sample locations and analyses. Precision levels of the analytical results based on Quality Control results shall also be available to the user.

7. Review Actions

The review function shall allow the following actions:

- Reviewer indicates agreement or disagreement with the test result.
- Reviewer requires a retest, where a retest is defined as a multiple of the original performance of the test.
- The results from a retest shall be associated with the original sample identification and test code.
- Reviewer requests that the sample be collected from the same location again to rerun the test. This new sample will be associated with the original sample even if assigned a new sample number.

8. Review Actions Affect Status

Actions by the reviewer shall automatically update the status of samples and tests.

Test Result Management	**REF**	**C**	**DC**	**CWM**	**Remark**
Permit the entry of comments	**1**				
Permit the user to enter an explanation in textual format to describe unusual conditions or circumstances	**1**				
Indicate that associated text exists when text has been added to explain a test result.	**1**				
Support calculations based on the results of multiple analyses and perform reasonableness checks on the computed results for multiple analyzers.	**2**				
Allow userdefinable regulatory limits or other limits with each sampling location	**3**				
Use result limits to check results and flag the user during result entry regarding adherence to limits.	**3**				
Permit multiple sets of limits per sampling location	**4**				
Allow an authorized user to review test result	**5**				
Permit review of test results based on:					
• Individual test code	**5**				
• Individual and range of sample ID code	**5**				
• Analytical result date	**5**				
• Bench sheet	**5**				

Precision levels of the analytical results based on quality control results shall be available to the user	**6**				
Allow the user to view historical results for sample locations and analyses.	**6**				
The review function shall allow the following actions:					
• Agreement or disagreement with test result	**7**				
• Requires a retest	**7**				
• Retest shall be associated with original sample identification and test code	**7**				
• Sample to be recollected from the same location and reanalyzed	**7**				
Actions by reviewer shall automatically update the status of samples and tests	**8**				

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